

**PIMA COUNTY DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR PROGRAM**

33. N. Stone Avenue, Suite 700 • Tucson, AZ 85701 • Phone: (520) 724-7400

AIR QUALITY PERMIT
(As required by Title 17.11, Article II, Pima County Code)

ISSUED TO

**BECTON, DICKINSON AND COMPANY (BD)
7345 E. VALENCIA ROAD
TUCSON, AZ 85747**

This air quality permit does not relieve applicant for meeting all air pollution regulations

**THIS PERMIT ISSUED SUBJECT TO THE GENERAL AND SPECIFIC
TERMS AND CONDITIONS IN THIS PERMIT**

PERMIT NUMBER: 6257

PERMIT CLASS: II

ISSUED: MAY 16, 2022

EXPIRES: MAY 15, 2027



SIGNATURE

Rupesh Patel, Air Program Manager, PDEO
TITLE

TABLE OF CONTENTS

Permit Section	Page
<u>Permit Summary</u>	4
<u>General Conditions</u>	
§ <u>1</u> : General Provisions (See Attachment 3).....	6
§ <u>2</u> : Definitions (See Attachment 3).....	6
<u>Specific Conditions</u>	
§ <u>3</u> : Permit Applicability	7
<u>30</u> . Statutory Authority and Compliance	7
<u>31</u> . Permit Classification	7
<u>32</u> . Permitted Sources & Sections.....	7
<u>33</u> . Applicability of more than one standard.....	8
§ <u>4</u> : Emission Limits and Standards	8
<u>40</u> . Permit-Wide Limits.....	8
<u>41</u> . General Control Requirements.....	8
<u>42</u> . Operation and Maintenance Requirements	8
<u>43</u> . Opacity	9
<u>44</u> . Visibility.....	9
<u>45</u> . NESHAP Subpart O (See Attachment 4).....	10
<u>46</u> . Voluntary Facility Emission Cap	10
<u>47</u> . Ancillary Operations – Boilers & Generators (See Attachment 6).....	13
§ <u>5</u> : Compliance Determination	14
§ <u>5a</u> : Monitoring and Recordkeeping	14
<u>50</u> . General Recordkeeping.....	14
<u>51</u> . Permit-Wide	14
<u>52</u> . NESHAP Subpart O (See Attachment 4).....	15
<u>53</u> . Voluntary Facility EO Emission Limit and Cap	15
a. Facility EO Emission Cap Monitoring.....	15
i. APC 1 – 8	15
ii. Specific Requirements for APC 1 & 2	15
iii. Specific Requirements for APC 3 – 8	16
iv. Data Handling Requirements	16
b. Recordkeeping/Records	16
§ <u>5b</u> : Instrumental Monitoring and Testing	17
<u>54</u> . NESHAP Subpart O (See Attachment 4).....	17
<u>55</u> . Facility EO Emission Cap	17
§ <u>5c</u> : Reporting Requirements	19
<u>56</u> . Permit-Wide	19
<u>57</u> . NESHAP Subpart O (See Attachment 4).....	20
<u>58</u> . Special Monthly Report for Public Access	20

Permit Summary & General Conditions

Attachment 1: Applicable Regulations.....21
Attachment 2: Equipment List.....24
Attachment 3: General Conditions (1 – 22).....30
Definitions.....41
Attachment 4: NESHAP Subpart O [Specific Applicable Conditions].....54
Attachment 5: Summary of Monitoring, Recordkeeping, and Reporting Requirements.....68
Attachment 6: Additional Ancillary Equipment Requirements.....70
Attachment 7: Approved O & M Plans for APC and CMS.....71

Permit Summary

(Unless otherwise noted, references in this permit are to Title 17 of the Pima County Code (PCC), Arizona Revised Statutes (ARS), Arizona Administrative Code (AAC), and the Pima County State Implementation Plan (SIP). Underlined text are hyperlinked references to either definitions in § 2 of this permit, Conditions within the permit, or to external websites containing the referenced provision.)

PERMIT SUMMARY

Location Information

This individual air quality permit is issued to Becton, Dickinson and Company (BD), the Permittee, for their operations to be located in Century Park Marketplace on 7345 E. Valencia Road, Tucson, AZ 85747 (Parcel ID 141-06-020D).

Source Description

Becton, Dickinson and Company (BD) is a registered corporation on file with the Arizona Corporate Commission (ACC ID# 23202622). BD is a global medical technology company with more than 70,000 associates serving in over 190 countries, operating over 20 sterilization sites globally, 12 of which are ethylene oxide sterilization facilities. This permit authorizes the construction and operation of its proposed new ethylene oxide sterilization facility for the purpose of sterilizing various medical products, including surgical kits, intravenous (IV) catheters and sets, surgical and vascular preparatory devices, and various types of syringes.

The pollutant-emitting activities and operations covered by this permit that constitute the facility and installations fall under the following industrial classification:

- Product Sterilization – SIC code 7389 – (NAICS 561910) [PCC 17.04.340.A (41)]

This is a Class II permit and the facility is a “True Minor Source” of conventional pollutants and an area source of Hazardous Air Pollutants (HAPs) when considering the limitations in this permit and emissions from other sources at the facility aggregated under the same major group two digit SIC Code (73). The facility is subject to Voluntary Limitations under PCC 17.11.190.B and National Emission Standards for Hazardous Air Pollutants (NESHAP) Subpart O in 40 CFR Part 63.

Ethylene Oxide Sterilization Operations

Emissions of hazardous air pollutants from the proposed facility will consist primarily of ethylene oxide (C₂H₄O; Chemical Abstract Service - CAS No. 75-21-8; hereafter referred to as EO) that result from the use of EO as a sterilant in the processes to sterilize medical and surgical equipment.

The facility is designed around an approximate usage of 225 tons of EO per year. The primary EO “process” emissions from the sterilization chambers and associated aeration room operations (6 sterilization lines – consisting of 1 sterilization chamber and 2 aeration rooms for each line) will be controlled by two LESNI® ethylene oxide catalytic oxidation (cat-ox) abatement systems with independent discharge points. These systems use a catalyst to oxidize the process EO gas emissions at a set temperature of above 140° C and convert the gas into the byproducts of carbon dioxide and water prior to discharge to the ambient air. The LESNI® cat-ox abatement system has proven highly efficient at reducing EO process emissions and has been used in the global medical sterilization industry for many years and exceeds current EPA NESHAP Subpart O standards that apply to the US industry.

The LESNI® air pollution control (APC 1 & 2) discharge points are limited to not exceed 1 PPM_V at the discharge vent(s), per the design and NESHAP Subpart O. In addition, as described in the application, the LESNI systems are also subject to a voluntary facility EO emissions cap.

Permit Summary

In addition to the above process emissions, the potential fugitive EO emissions from facility operations will be effectively collected and controlled from the following distinct work areas interior to the building using Advanced Air Technology® dry bed system(s) with specialized dry chemi-sorbant media designed to reduce the EO emissions from the areas below (See Condition 46, the equipment list, and the technical support document (TSD) for more information):

- Area 1 – Gas Room Areas (includes the EO gas dispense room, day tanks, and vaporizer room). Emissions from Area 1 will be controlled using dry bed system(s) (APC 3). The emissions discharged from APC 3 are limited not to exceed 100 micrograms per cubic meter based on a one-hour average.
- Area 2 – Sterilization Chamber Areas (including the sterilization chamber rooms, and damage limiting construction (DLC) areas). Emissions from Area 2 will be controlled using dry bed system(s) (APC 4). The emissions discharged from this APC 4 are limited not to exceed 100 micrograms per cubic meter based on a one-hour average.
- Area 3 – Work In Progress (WIP) & Post-Sterile Warehouse Area. The aeration chambers are located in this area. Any fugitive from these chambers will be captured by the APCs located in Area 3. The area will be equipped with 4 independent APC systems. Emissions from this area will be controlled using 4 separate dry bed system(s), and the discharge concentration from each of these 4 APCs are limited not to exceed 200 micrograms per cubic meter based on a one-hour average.

The capture of the fugitive emissions will be monitored by the building ventilations system to ensure total enclosure and 100% capture efficiency.

Facility-Wide Ethylene Oxide Emissions Cap

To effectively control EO emissions from the facility, the Permittee has accepted an EO emissions cap of 709 lb/yr as a 12-month rolling total. Compliance with this cap will be monitored through use of a continuous emissions monitoring system (CEMS) for APC 1-8, monitoring of building parameters to ensure collection of EO fugitive emissions within the operational areas of the facility, and through a leak detection and repair program. The monitored emission rate data shall be reduced (as applicable), determined, and recorded for each operating day, and month to determine compliance.

Ancillary Operations

In addition to the principal sterilization operations, the facility will also operate an emergency generator, an emergency engine driven fire pump, and fossil-fuel fired industrial and commercial equipment (Boilers & Heaters). Both the emergency generator and fire pump that are subject to New Source Performance Standards (NSPS) in the Code of Federal Regulations 40 CFR Part 60. These operations are covered under PDEQ's GP for Fuel Burning Equipment.

GENERAL CONDITIONS

§ 1: General Provisions: See Attachment 3

§ 2: Definitions: See Attachment 3

Permit Revision

This permit authorizes the construction or modification and operation of the facility and its equipment/operations described in this permit and the application on file with the Control Officer. To revise this permit, the Permittee must submit a complete application to the Control Officer by mail, e-mail, or hand delivery to the address listed in Condition 11.a.ii, and prior to issuance; pay the applicable fee pursuant to Condition 8. (See Condition 14 regarding facility changes and criteria governing permit amendments/revisions).

Permit Termination

Condition 6 of this permit addresses the Control Officer’s ability to revise, revoke and reissue, or terminate this permit. The Permittee may also voluntarily request termination of this permit per PCC 17.13.060.

Emission Limitations

This permit may impose limitations to ensure that the source remains a minor source with emission rates below the major source threshold for conventional pollutants, the area source threshold for hazardous air pollutants (HAPs), or to avoid other applicable requirements. The equipment list describes the permitted equipment, operations, and/or activities and references to the permit sections (§§) containing the specific terms and Conditions that apply. The equipment list may include operational limitations or parameters to be monitored, and reference specific attachments/requirements for additional ancillary operations.

Emissions Summary

The following emission rates are for reference purposes and are used to establish whether or not the source is a major source in terms of the Title V permit program. They reflect the maximum allowable emissions rate of pollutants from the regulated sources under the limits and standards in this permit and associated application. They are not intended to be enforced by direct measurement unless otherwise noted in the Specific Conditions of the permit. (See the TSD for more details on the facilities controlled and uncontrolled potential to emit (PTE)).

Table 1: Facility Wide Emissions of <u>Pollutants</u> (tons/yr)												
Source Type and Category	<u>Conventional or Criteria</u> Air Pollutants								NSPS or NESHAP Pollutants	<u>HAP(s)</u>		CO₂e
	PM_{2.5}	PM₁₀	PM	NO_x	VOC	CO	SO₂	Pb	EO	Total	Single	
Sterilization ¹	-	-	-	-	0.36	-	-	Neg.	0.36	0.36	0.36	-
Boilers	0.82	0.82	0.82	1.17	0.59	3.97	0.06	Neg.	-	0.20	< 0.2	4190
Fire Pump	0.00	0.00	0.00	0.01	0.00	0.07	0.03	Neg.	-	-	-	5.7
Generator	0.00	0.00	0.00	0.03	0.01	0.28	0.00	Neg.	-	0.00	0.00	20.4
Total Estimated Emissions	0.82	0.82	0.82	1.21	0.96	4.33	0.09	Neg.	-	< 0.56	< 0.56	4214

¹Note: These are the estimated of point source emissions from the LESNI and Advanced Air Technology® dry bed air pollution control devices (APC) under the maximum allowances in this permit. See the TSD for more detailed emission estimates, emission points, and the facility wide EO emission cap.

Permit Terms and Conditions

All terms and Conditions in this permit that are Federally Enforceable or Material Permit Conditions are specifically indicated as such. Federally Enforceable terms and Conditions also include all references to 40 CFR.

SPECIFIC CONDITIONS

§ 3: Permit Applicability

30. Statutory Authority and Compliance [PCC 17.11.010.B & D, PCC 17.11.190, PCC 17.13.010, and ARS § 49-480]

- a. Ambient air pollutant emissions from the facility, specifically the emissions from the equipment and operations described in the equipment list that fall under SIC Code 7389 (NAICS 561910) are subject to the enforceable limitations in this permit and any applicable general permits. This permit is issued pursuant to ARS § 49-480 and authorizes the construction or modification and operation of the facility, equipment and operations described in the equipment list. This authorization is based on the regulations in effect on the date of issuance of this permit, and a finding that the allowable emissions from the facility, specifically the emissions from the equipment and operations more fully described in the application on file with the Control Officer:
 - i. Do not constitute a "major source" within the meaning defined in PCC 17.04.340.A.128; and
 - ii. Will neither cause nor contribute to a violation of any ambient air quality standard; and
 - iii. Are adequately protective of the public's health, safety, and general welfare over a potential lifetime of exposure.
- b. Notwithstanding the above findings, this permit shall not relieve the Permittee from compliance with all local, county, state and federal laws, statutes, and codes or from compliance with any conditional orders issued by the Control Officer pursuant to this permit and Chapter 17.28 of Title 17 of the PCC.
- c. Should any conditions at the facility, or any federal, state, or local rules or findings change such finding, the Permittee or Control Officer shall submit a report of such finding and proceed to reopen and revise the permit in accordance with Conditions 6.b and 14.

31. Permit Classification [PCC 17.04.340.A (30) (41), (134), (175), (221); and PCC 17.11.090]

Class II – True Minor Source. The facility is a Minor Source of conventional pollutants and an area source of HAP's, when considering the limitations in this permit, any applicable attachments, and emissions from other sources at the facility aggregated under the same major group two digit SIC Code (73). The facility is subject to NEHSAP Subpart O in 40 CFR Part 63.

32. Permitted Sources & Sections [PCC 17.04.340.A (41), PCC Articles IV, VI, and VII of Chapter 17.16]

The Specific Conditions in this permit apply to the facility, equipment and operations listed in the equipment list. Refer to Attachment 2 of the TSD for information relating to specific applicability determinations. The Specific Conditions and source categories are arranged into the following permit Sections (§§):

- § 3: Permit Applicability (This Section);
- § 4: Emission Limitations and Standards;
- § 5: Compliance Determination;
- § 5a: Monitoring and Recordkeeping;
- § 5b: Testing;
- § 5c: Reporting Requirements;

Attachment 1: Applicable Regulations;

Attachment 2: Equipment list;

Attachment 3: General Conditions;

Attachment 4: NESAP Subpart O

Attachment 5: Summary of Monitoring, Recordkeeping, and Reporting Requirements;

Attachment 6: Ancillary Equipment Attachments (Boilers & Generators)

33. **Applicability of more than one standard** [PCC 17.16.010.B]
[**Federally Enforceable Condition**]

If more than one emission limit or emission standard in this permit is applicable to the same source, the more stringent standard or emission limit shall apply.

§ 4: Emission Limitations and Standards [PCC 17.13.020.A.2]

40. **Permit-Wide Limits** [Material Permit Conditions]

- a. When so indicated in the equipment list of this permit, the Permittee shall monitor and restrict or limit the operation of emission sources to the respective parameters, limits, or throughputs.
- b. The Permittee shall monitor and keep records demonstrating that the emission rate of air pollutants from sources covered under this permit, and any other permitted sources located within the contiguous or adjacent areas under the common control of the same person, do not exceed the major source threshold.

41. **General Control Requirements** [Federally and Locally Enforceable Conditions]

- a. The Permittee shall comply with permit-wide operations standards contained in Title 17 and as provided in General Permits (GP's) issued by the Control Officer (See Attachment 6 for applicable GP's).
- b. Where a stack, vent or other outlet is at such a level that fumes, gas mist, odor, smoke, vapor or any combination thereof constituting air pollution are discharged to adjoining property, the Control Officer may require the installation of abatement equipment or the alteration of such stack, vent or other outlet by the Permittee to a degree that will adequately reduce or eliminate the discharge of air pollution to adjoining property. The alteration may be determined by use of good engineering practice (GEP) stack height or such other approved measures. [PCC 17.16.020.B, PCC 17.11.150]
- c. The Permittee shall not construct, install, erect, use, replace, modify, or operate an emission source so as to conceal an emission which would otherwise be a violation of a standard in this permit. [PCC 17.20.040]
[**Federally Enforceable Condition**]

42. **Operation and Maintenance Requirements** [PCC 17.13.020.A3.d, PCC 17.13.200.B.2, PCC 17.16.020.A]
[**Federally Enforceable for Sources Subject to NSPS and NESHAPs**]

- a. At all times, including periods of startup, shutdown, and malfunction, the Permittee shall to the extent practicable maintain and operate each source covered by this permit, including any associated APC or monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. [40 CFR 60.1(a) & 40 CFR 60.11(d)][40 CFR 63.6(a) & 40 CFR 63.6(e)]
- b. Determination of whether acceptable operating and maintenance (O & M) procedures are being used will be based on information available to the Control Officer which may include, but is not limited to, monitoring results, opacity observations, review of operating and maintenance procedures (including the startup, shutdown, and malfunction plan, when required), review of operation and maintenance records, and inspection of the source. [40 CFR 60.11(d) & 40 CFR 63.6(e)]
- c. The Control Officer may require the Permittee to develop, submit, and follow an approved O & M plan for permitted sources (including any startup, shutdown, and malfunction plans per NESHAP 40 CFR Part 63) prior to initial start up the source. Any monitoring or recordkeeping requirements in an approved O & M plan under this provision shall be enforceable as a practical matter. [PCC 17.13.020.A.3.d][40 CFR 63.6(e)]

43. Opacity

[Federally Enforceable when Opacity > 40%]

- a. Except for open fires permitted pursuant to Condition 19.b and sources located within the boundaries of the Tohono O’Odham, Pasqua Yaqui, and San Xavier Indian Reservations, the opacity of emissions from nonpoint sources shall not exceed the following: [PCC 17.16.050.B.& C]
 - i. 20% for such nonpoint sources in eastern Pima County, east of the eastern boundary of the Tohono O’Odham Reservation.
 - ii. 40% for such nonpoint sources in all other areas of Pima County.
- b. The average optical density of plumes and effluents from a single point, multiple emission point, or fugitive emission source shall not exceed 20% opacity, unless otherwise specified in PCC Table 17.16.040 or this permit. [PCC 17.16.040 & Table PCC 17.16.040, PCC 17.16.130.B.1]
- c. In accordance with the procedures in Condition 15.a.ii.(a), opacity (optical densities) of an effluent shall be measured by a certified visible emissions evaluator with his/her natural eyes or with certified equipment, approximately following the procedures which were used during his/her certification, or by an approved and precisely calibrated in-stack monitoring instrument. [PCC 17.16.040.A.1]
- d. A violation of an opacity standard shall be determined by measuring and recording a set of consecutive, instantaneous opacities, and calculating the arithmetic average of the measurements within the set unless otherwise provided in this permit. The measurements shall be made at approximately fifteen-second intervals for a period of at least six minutes, and the number of required measurements shall be as specified in PCC Table 17.16.040. Sets need not be consecutive in time, and in no case shall two sets overlap. If the average opacity of the set of instantaneous measurements exceeds the maximum allowed by any rule, this shall constitute a violation. [PCC 17.16.040.A.2]
- e. The use of air or other gaseous diluents solely for the purpose of achieving compliance with an opacity standard is prohibited. [PCC 17.16.040.A.3]
- f. When the presence of uncombined water is the only reason for failure of a source to otherwise meet the requirements as specified in Conditions 43 and 44.b, Conditions 43 and 44.b shall not apply. [PCC 17.16.040.B]

44. Visibility

[PCC 17.16.050]

- a. The Permittee shall not cause, suffer, allow or permit operations or activities likely to result in excessive amounts of airborne dust without taking reasonable precautions to prevent excessive amounts of particulate matter from becoming airborne in accordance with all applicable provisions Article III of Title 17. [PCC 17.16.050.A]
- b. The Permittee shall not cause, suffer, allow, or permit diffusion of visible emissions, including fugitive dust, beyond the property boundary line within which the emissions become airborne, without taking reasonably necessary and feasible precautions to control generation of airborne particulate matter in accordance with the fugitive dust emission standards in Article III of Title 17. Sources may be required to cease temporarily the activity or operation which is causing or contributing to the emissions until reasonably necessary and feasible precautions are taken. [Federally Enforceable Condition]
- c. Taking reasonably necessary and feasible precautions as prescribed in Conditions 44.a and b shall be considered compliance with the fugitive dust provisions in Condition 44.b.

- d. Condition 44.b shall not apply when wind speeds exceed twenty-five (25) miles per hour (using the Beaufort Scale of Wind-Speed Equivalents, or as recorded by the National Weather Service). This exception does not apply if control measures have not been taken or were not commensurate with the size or scope of the emission source. [PCC 17.16.050.D.2]
- e. Condition 44.b shall not apply to the generation of airborne particulate matter from undisturbed land. [PCC 17.16.050.D.3]

45. NESHAP Subpart O – (See Attachment 4) [Federally Enforceable Conditions]

The Permittee shall comply with all applicable provisions of the National Emission Standard for Hazardous Air Pollutants (NESHAP) as found in 40 CFR 63 Subpart O – “Ethylene Oxide Emission Standards for Sterilization Facilities,” for the operation of sterilization sources at the facility.

46. Voluntary Facility EO Emission Limits and Cap

The EO emission control provisions below apply permit-wide and to the referenced APC systems pursuant to the application on file with the Control Officer and as listed in Table 1 of the equipment list (See Attachment 2 of this permit).

- a. Facility EO Emission Cap [PCC 17.11.190.B, PCC 17.13.070, PCC 17.11.120.A.3.a]
[Federally Enforceable & Material Permit Conditions]

The Permittee shall not exceed the following EO emission cap calculated monthly as determined from continuous monitoring data of APC 1-8 pursuant to Conditions 53.a and 55:

- i. 709 lb/yr of EO as a 12-month rolling total.
- ii. Each month the total actual facility emissions to the atmosphere shall be determined using the CEMS monitoring data and calculated and recorded in a “Facility Cap Spreadsheet” using the procedures in Condition 53.a to demonstrate compliance according to the following formula:

$$E_{Total} = E_1 + E_2 + \dots E_n + L$$

Where;

E_{Total} = Total pounds of EO emitted by the facility

E_n = Total pounds of EO emitted from exhaust to atmosphere of APC_n

L = Total pounds of EO emitted from any leaks, or emergency room ventilations documented as provided in Condition 46.b.ii(d).

- b. The Permittee shall install, operate, and maintain the Advanced Air Technologies APC described in Table 2 and the equipment list (Attachment 2 of this permit) to effectively collect and control fugitive EO emissions to levels less than the limits in Table 2 and shall operate the APC at all times the facility is in operation: [PCC 17.11.190.B, PCC 17.11.120.A.3.c & d]
[Federally Enforceable & Material Permit Conditions]

- i. Prior to initial startup, the Permittee shall submit for the Control Officer’s approval, an operations and maintenance (O&M) plan in accordance with Condition 42.c. In accordance with Condition 14.c, should the Control Officer or Permittee require, propose, or request a revision or modification to the approved O & M plan, it may be revised without a re-opening of the permit.

[Note to Condition 46.b.i: As provided in Condition 13.b, the Permittee may claim confidentiality on any necessary elements, sections or pages, of the O & M Plan if disclosure of such information would cause or likely cause substantial harm. Upon a satisfactory showing of such claim to the Control Officer, and an affirmative determination by the County Attorney, the Control Officer shall hold such claimed information confidential in accordance with PCC 17.11.070 B, 17.24.010, or any other applicable law.]

- ii. The O & M plan shall include, address and establish records and procedures for, the following: [PCC 17.13.020.A.2]
- (a) Verification of proper operation and integrity of the APC and associated monitoring systems to include but not limited to the following:
- (i) Chosen CEMS system to fulfill emissions monitoring requirements, quality assurance (QA) and quality control (QC) procedures to include an annual relative accuracy test audit (RATA) per Condition 55.b; and
[Note: The Control Officer recommends use of NSPS 40 CFR Part 60, Appendix B, PS – 6 and 8 and any additional specific vendor recommendations as a guideline to develop the QA/QC monitoring plan.]
- (ii) For the dry bed systems in Table 2 below:
- (A) Daily pressure differential (pressure drop) measured across each dry bed system; and
- (B) Periodic visual inspection of the dry bed media; and
- (C) Periodic Maintenance of the fans, ducting, and control systems.
- (b) The tracking of daily, and monthly emissions and performance of each APC in Table 2 below for compliance and to document the following:
- (i) Applicable building management system parameters that demonstrate 100% capture efficiency for Areas 1, 2, and 3 controlled by APC 3-8 as provided in Condition 46.b.ii(c) and average times or duration doors were open and negative pressure indicators were zero or positive;
- (ii) Amount of EO used since installation or previous media change-out, and remaining capacity of the dry-bed media;
- (iii) Logs of maintenance performed;
- (iv) Hours of operation and times removed from service for maintenance or other reasons. Times the facility is not operating and times units are shutdown shall be recorded;
- (v) Deviations, or malfunctions from proper function, their duration, and any corrective actions taken to restore units or monitored parameter to their proper function;
- (c) A report of the design, to include the identification of periodic measurements and parameters to be collected and monitored by the building management system, that demonstrate proper collection (capture) of fugitive EO emissions from areas downstream of any natural draft openings and outer or peripheral areas, so as to create a total enclosure. Compliance shall be monitored and demonstrated to meet the following elements:
- (i) All doors and openings to the areas listed in Table 2 shall be kept closed except when in use. Door status will be monitored by the building security system.
- (ii) The operational status of the APC (Area's 1, 2 and 3 airflows) will be monitored by the building management system.

- (iii) The areas shall be maintained at negative pressure per the facility design. Times and duration of any malfunction of the negative air conditions shall be monitored by the building management system.

- (d) The Permittee shall develop, implement and maintain an EO Leak Detection and Repair (LDAR) Program. The Program shall check all outside components (valves, flanges, fittings, drums, etc.) for leaks. The initial program shall be submitted no later than 30 days before first use of EO in the sterilization chamber. The program shall identify procedures to record and document any leaks and any necessary uncontrolled emergency ventilations to the atmosphere.

Condition 46, Table 2 – APC¹ Emission & Operating Limits, and Monitoring Frequency

Description	Emission and Operating Requirements	Monitoring Frequency ² ,
<p>Source ID 07 – Area 1 Gas Room Areas;</p> <ul style="list-style-type: none"> The gas dispense (day tank) room(s); Vaporizer room(s); 	<p>Source ID 07, APC – 3</p> <p>EO Limits: 100 µg/m³ as a 1 hour average</p> <p>Compliance with the limits shall be monitored hourly in accordance with Condition <u>53.a.iii</u>.</p>	<p align="center">Continuous</p>
<p>Source ID 08 –Area 2 Sterilization Areas;</p> <ul style="list-style-type: none"> Chamber Rooms 	<p>Source ID 08, APC – 4</p> <p>EO Limits: 100 µg/m³ as a 1 hour average</p> <p>Compliance with the limits shall be monitored hourly in accordance with Condition <u>53.a.iii</u>.</p>	<p align="center">Continuous</p>
<p>Source ID 09 – Area 3 Post-Sterilization Area,</p> <ul style="list-style-type: none"> Work-In-Progress Warehouse (WIP) Post Sterile Area 	<p>Source ID 09, APC – 5</p> <p>EO Limits: 200 µg/m³ as a 1 hour average</p> <p>Compliance with the limits shall be monitored hourly in accordance with Condition <u>53.a.iii</u>.</p>	<p align="center">Continuous</p>
	<p>Source ID 10, APC – 6</p> <p>EO Limits: 200 µg/m³ as a 1 hour average</p> <p>Compliance with the limits shall be monitored hourly in accordance with Condition <u>53.a.iii</u>.</p>	<p align="center">Continuous</p>
	<p>Source ID 11, APC – 7</p> <p>EO Limits: 200 µg/m³ as a 1 hour average</p> <p>Compliance with the limits shall be monitored hourly in accordance with Condition <u>53.a.iii</u>.</p>	<p align="center">Continuous</p>
	<p>Source ID 12, APC – 8</p> <p>EO Limits: 200 µg/m³ as a 1 hour average</p> <p>Compliance with the limits shall be monitored hourly in accordance with Condition <u>53.a.iii</u>.</p>	<p align="center">Continuous</p>

¹ APC – Air Pollution Control System(s) see equipment list for referenced systems.

² Monitoring shall be conducted pursuant to provisions in Conditions 46.b.i, 53, and 55.

47. Ancillary Operations (Boilers & Generators)

The Permittee shall comply with applicable provisions contained in the general permit (GP) for Fuel Burning Equipment pursuant to the authorization for coverage in the equipment list and the applicable Conditions as provided in Attachment 6 of this permit. [PCC 17.13.020.A.2, PCC 17.13 Article I]

48-49. [Reserved]

§ 5: Compliance Determination

[PCC 17.13.020.A.3, 4, & 5]

§ 5a: Monitoring and Recordkeeping

[PCC 17.13.020.A.3 & 4]

50. General Recordkeeping

[PCC 17.13.020.A.3 & 4]

All records required by or generated to verify compliance with provisions in § 5 shall be maintained in accordance with Condition 12.

51. Permit-Wide

[PCC 17.13.020.A.3 & 4]

a. Unless otherwise indicated in this permit, the Permittee shall monitor each appropriate period the parameters identified in the equipment list (Attachment 2 of this permit) for each source indicated. The Permittee shall keep monthly and 12-consecutive month totals or averages (as applicable) of operating parameters, limits or throughputs per Condition 40.

b. Visible Emissions

i. If at any time, or while conducting an opacity check required by this permit, the Permittee sees any plume or effluent from an emission source at the facility, that on an instantaneous basis appears to exceed the opacity limit, or if visible emissions including fugitive dust, diffuse beyond the property boundary line, the Permittee shall investigate the source of the emissions and, if required, take corrective action. If the plume persists, or the equipment, activity, operation, or conditions causing or contributing to the emissions cannot be corrected or halted, when practicable, the Permittee shall make a visible emission evaluation of the opacity (VE) in accordance with Condition 43.c and maintain a record of the results. If the VE determination exceeds the applicable opacity limit, or if visible emissions, including fugitive dust, diffuse beyond the property boundary line, the Permittee shall report this as an excess emission in accordance with Condition 11.

[PCC 17.16.040 & PCC 17.16.50.B]

ii. The Permittee shall keep and maintain records of any VE opacity determinations made pursuant to Conditions 15.a.ii.(a) and 51.b.

iii. The Permittee shall document and keep records of all opacity checks required by this permit or attachment, or when requested by the Control Officer, including any investigation or corrective action taken to comply with the opacity and visibility standards pursuant to Conditions 43 and 44.

c. When requested by the Control Officer or required by this permit or attachment, the Permittee shall keep records pursuant to Condition 44.b of the necessary and reasonable precautions taken to control fugitive dust from operations at the facility.

d. The Permittee shall keep copies of any required activity permits per Condition 19 obtained by the Permittee or subcontractors and associated records.

e. Except as provided in Conditions 7, 9, 11, 12, 14, 15.e, 15.h, 19, and 45, 46, 47, and or in Attachment 6 to this permit, additional monitoring for compliance with Conditions 40 through 44 shall not be necessary.

f. The Control Officer may request that the Permittee conduct additional monitoring if there is reasonable cause to believe the Permittee may be in violation of the standards in Conditions 40 through 44.

g. See Attachment 5 for a summary of the monitoring, recordkeeping, and reporting required by this permit. See Attachment 7 of the permit for applicable O & M plan requirements.

52. NESHAP Subpart O (See Attachment 4)

[40 CFR 63.363, 364, 367, PCC 17.13.020.A.3 & 4]

[Federally Enforceable Conditions]

The Permittee shall comply with all applicable provisions of the National Emission Standard for Hazardous Air Pollutants (NESHAP) as found in 40 CFR 63 Subpart O – “Ethylene Oxide Emission Standards for Sterilization Facilities,” for the operation of sterilization sources at the facility.

53. Voluntary Facility EO Emission Limits and Cap

[PCC 17.11.190.B, PCC 17.13.070 & PCC 17.11.120.A.3.a]

[Federally Enforceable & Material Permit Conditions]

a. Facility EO Emission Cap Monitoring

- i. While operating, the emissions to the atmosphere from APC 1 – 8 shall be continuously monitored each calendar day to determine compliance with the limits in Conditions 46.a.i according to the following:
 - (a) Required monitoring devices shall be installed prior to startup such that representative measurements of emissions and associated process parameters are obtained in accordance with Conditions 46.b.ii(a)(i) and Condition 55. For monitoring equipment purchased from a vendor, verification of the operational status of such equipment shall include completion of the manufacturer’s written specifications or recommendations for installation, operation, and calibration.
 - (i) Upon startup, the Permittee shall operate a dedicated CEMS and obtain 1-hour monitoring data in accordance with the provisions below. For compliance purposes, the data collection requirements in Condition 53.a.ii and iii below shall apply 180 days after startup.
 - (ii) Deviations from the CEMS monitoring data collection requirements shall be reported per Condition 56.a.i(b).
 - (iii) Invalid or missing CEMS data periods shall be substituted with the PTE values in the table in Condition 53.a.iv(b) below.
 - (b) Emission rates shall be obtained at least once every 15 minutes using the CEMS. The amount of EO emitted shall be determined for each APC, for each operating hour, day and month. The monthly emission data for each APC shall be used to determine compliance with the Facility Emission Cap according to the formula in Condition 46.a.ii and recorded in the “Facility Cap Spreadsheet”.
 - (c) The Permittee shall install pitot-type flow monitoring devices to monitor the flow rate from the APC discharge points to calculate the mass of EO emitted monitored each hour by the CEMS.

[PCC 17.11.120.A.3.b]

 - (i) For invalid or missing flow monitor data the Permittee shall use the maximum flow rate capacity in the equipment list.
- ii. Specific Monitoring and Reporting Requirements for APC 1 & 2
 - (a) Should monitored emissions exceed the applicable limits required by Subpart O during sterilization and aeration chamber validation, the Permittee shall investigate and correct system controls until such time that the system complies with the emission limits.
 - (b) Monitoring data shall be collected for no less than 75% of the operating hours per day for at least 90% of the operating days per 12-month period to determine compliance.
 - (c) Any periods of operation where both the catalyst bed temperature, **and CEMS** monitoring data are unavailable or during malfunction, shall be re reported as excess emissions per Condition 11.c.

iii. Specific Monitoring and Reporting Requirements APC 3 – 8

- (a) Should the monitored emissions exceed the applicable limits in Table 2 of Condition 46, the Permittee shall report an excess emission in accordance with Condition 11. The Permittee shall investigate and report all such excess emissions and correct the condition as soon as possible but no longer than 60 days following such exceedance
- (b) Any periods of operation where both the dry bed pressure drop, **and** CEMS monitoring data are unavailable or during malfunction, shall be reported as excess emissions per Condition 11.c.
- (c) Monitoring data shall be collected for no less than 75% of the operating hours per day at least 90% of the operating days per 12-month period to determine compliance.

iv. Data Handling Requirements

- (a) All monitored exceedances of the standards in Condition 45.b.i or Condition 46.b, the Permittee shall be required to apply toward compliance with the Facility EO emission cap as provided in Condition 53.b.ii, unless an investigation into the exceedances would otherwise alter such a finding.
- (b) The Permittee shall use the following maximum controlled facility PTE values for periods of missing or invalid hourly CEMS monitoring data during missing data periods that are not otherwise during uncontrolled emissions or during APC malfunction:

APC	PTE Data Values, lb/hr [x 10 ⁻³]
1	5.14
2	5.14
3	1.48
4	9.02
5	15.04
6	15.04
7	15.04
8	15.04

- (c) Each day the calculated emissions exceed the cap in Condition 46.a.i shall be considered a violation and exceedance in accordance with Condition 11.a.
- b. Recordkeeping: The following records and documentation shall be kept in a complete and consistent manner and the Permittee shall make them available for review without delay during normal business hours. **[Federally Enforceable – 2-year retention]**
- i. The Permittee shall monitor and record the EO usage of the facility at least once each month and calculate a 12-month rolling total. **[Federally Enforceable Condition]**
 - ii. Facility EO Cap Spreadsheet
- For each APC, the Permittee shall maintain records of the daily averages for each operating day and the monthly emissions. The facility emissions will be entered in the spreadsheet within 20 days of the end of the month.
- (a) For purposes of initial compliance with the 12-month rolling total, on month 1 – initial startup, the 11 preceding months shall be assumed to be zero to represent non-operation of the facility.
 - (b) In addition to the “Facility Cap Spreadsheet” containing the 12-month rolling total facility EO emissions, the Permittee shall maintain a file of any raw monitoring data (as applicable) and the reduced operating day and month EO emissions from each APC (1 – 8).

- iii. A copy of the approved O & M Plan with current schedules of periodic parametric monitoring, inspection forms, and procedures and files documenting the following:
 - (a) Chosen CEMS system to fulfill compliance monitoring and requirements per Condition 46.b.ii(a)(i).
 - (b) Daily pressure differentials and 12-month average; and other periodic parametric monitoring and inspection forms (as applicable), to include periodic visual inspections of the dry bed media, emission rate tracking, and determination of remaining media capacity units of tons of EO usage before media change-out;
 - (c) Applicable building management system parameters monitored for Areas 1, 2, and 3 as provided in Condition 46.b.ii(c) and average times or duration doors were open and negative pressure indicators were zero or positive.
 - (d) Maintenance logs and records for each APC, fan, ducting and control system;
 - (e) Logs of deviations and malfunction from operating parameters, their duration; and corrective actions taken to restore APC units or monitored parameters to their proper function.
 - (f) Hours of operation and times removed from service for maintenance or other reasons; and
 - (g) The Permittee shall develop, implement, and maintain an ethylene oxide Leak Detection and Repair (LDAR) Program. The LDAR Program shall check all outside components (valves, flanges, fittings, drums, etc.) for leaks . The initial program shall be submitted to the Control Officer, in writing, no later than 30 days before first use of ethylene oxide in the sterilization chamber.

§5b: Instrumental Monitoring and Testing

[PCC 17.13.020.A.3]

54. NESHAP Subpart O (See Attachment 4)

[40 CFR 63.365]

[**Federally Enforceable Conditions**]

The Permittee shall comply with all applicable provisions of the National Emission Standard for Hazardous Air Pollutants (NESHAP) as found in 40 CFR 63 Subpart O – “Ethylene Oxide Emission Standards for Sterilization Facilities,” for the operation of sterilization sources at the facility.

55. Facility EO Emission Cap

[PCC 17.11.190.B, PCC 17.13.070 & PCC 17.11.120.A.3.b]

[**Federally Enforceable & Material Permit Conditions**]

[Note: Nothing in the following conditions shall be construed so as to require or prohibit any specific CEMS monitoring instrument, monitoring strategy, or facility design to combine exhaust stacks prior to discharge; so long as such monitoring device can measure/sample the expected emission concentrations from each stack at least once every 15 minutes, and with a lower detection level threshold sufficient to allow a compliance determination.]

- a. Prior to startup, the Permittee shall install, calibrate, certify and maintain a dedicated continuous emission monitoring system (CEMS) to monitor the emission rates of EO to the atmosphere from APC 1 – 8 as required in Condition 46 and in accordance to the following, unless otherwise approved by the Control Officer or Administrator of the EPA:
 - i No later than sixty (60) days prior to the operation of the CEMS, the Permittee shall submit, in writing, an ethylene oxide CEMS monitoring plan. The plan, and any modifications to said plan, shall be subject to the review and approval by the Control Officer.
 - ii The installed CEMS shall be equipped with continuous flow rate monitoring systems, and any other necessary systems, for converting CEMS concentration data to a mass flow rate, and shall be operated in accordance with the approved monitoring plan.
 - iii To monitor compliance, the EO concentration shall be measured and recorded in units of micrograms per cubic meter ($\mu\text{g}/\text{m}^3$), parts per million by volume (PPM_v), or parts per billion by volume (PPB_v) and using concurrent measurement of the flow rates, an emission rate in lb/hr shall be determined.
 - iv The Permittee shall monitor emissions in accordance with Condition 53, and follow the QA/QC methods and procedures in Conditions 55.b-d.

- v During any Reference Method, RATA, or any other periodic sampling or testing or performance test required by this permit, the facility and APC operating parameters including the EO usage since installation or change-out of the dry bed control media or oxidation catalyst shall be documented with the test results.
 - vi The Permittee shall calibrate, certify and maintain the CEMS according to a performance specification for ethylene oxide within three (3) years following promulgation, should the U.S. EPA finalize such a performance specification.
- b. A RATA test to certify the continuous monitoring devices (CEMS and certified flow monitoring devices) shall be conducted within 180 days of startup, and may be used in lieu of any other performance test required by this permit and conducted annually in accordance with the proposed monitoring plan in Conditions 46.b.ii.(a)(i) and 55.a.i subject to the following QA testing procedures:
- i The dedicated CEMS shall be QA tested each quarter and require a relative accuracy test audit (RATA) of the instrument along with its associated digital acquisition and handling system (DAHS) to include the flow measurement monitor, and the mass emission rate determination, at least once every four calendar quarters; for each of the 3 calendar quarters following such annual RATA testing, a 2 – point cylinder gas audit (CGA’s) of the EO concentration measurement shall be required, with successive quarterly CGA’s occurring no closer than 2 months (See Note to Condition 46.b.ii(a)(i) for reference to the general performance specifications and methods to conduct such QA testing).
 - ii During the annual RATA test of the CEMS/DAHS system, outlet airflow parameters using EPA Methods 1, 2, and 4 shall be measured. If the flow monitor measurements recorded by the CEMS/DAHS are below the reference airflow test results, the CEMS/DAHS system and previous flow data shall be bias adjusted (normalized) to the reference method flow averages.
 - iii All RATA and CGA tests to certify the CEMS shall require the submittal of a notification in accordance with Condition 55.d below.
- c. For the purpose of complying with this permit, the Control Officer has approved the following methods and procedures (as appropriate) for measuring or monitoring the EO concentration for sources subject to this permit, provided the detection levels are within the range necessary to determine the expected source concentrations:
- i EPA Reference Methods 18 and/or 25A, 320, Alt 142 using Fourier Transform Infra-red (FTIR);
 - ii Gas analyzer’s utilizing cavity ring-down laser spectroscopy technology tuned to monitor EO;
 - iii TO-15A with Gas Chromatography/Mass Spectrometry (GC/MS) in the Selective Ion Monitoring (SIM) acquisition mode ¹;
 - iv TO-17 with GC/MS in SIM acquisition mode ¹.
- [Note: ¹“*Rapid Determination of Ethylene Oxide and 75 VOC’s in Ambient Air with Canister Sampling and Associated Growth Issues, Separations 2021 8, 35; Authors Jason Hoisington and Jason S. Erington*]
- d. When conducting periodic RA tests (RATA or CGA) tests to certify the CEMS or any other periodic testing required by this permit, the Control Officer shall require the submittal of a notification and test protocol in accordance with Condition 15.e. Once such test method protocol has been submitted and approved, upon request and by mutual agreement with the Control Officer, the Permittee shall only be required to notify the Control Officer of such testing.
- e. Following the first year after initial startup, and upon review and approval in accordance with Condition 15.h, if satisfied with periodic performance or certification testing results required by this permit for installed monitoring devices, by mutual agreement with the Control Officer, the Permittee shall not be required to submit the full written test reports and may thereafter provide results in a summary form to include the tested emission rate, test date, the monitored APC, the measured EO concentration, the approved test method, and the determined emission rate. Also by mutual agreement, the test results may be included in the annual summary report in Condition 56.a.i in lieu of being reported 30 days after

each PT as required by Condition 15.h. Notwithstanding said waivers, the Permittee shall be required to maintain the full written test reports on site for inspection and review by the Control Officer and to submit any such reports upon request.

- f. The Permittee shall be required to maintain the full written test reports, or monitoring data of any onsite testing and/or monitoring conducted in accordance with this permit available for inspection and review, and to submit such reports upon request.

§ 5c: Reporting Requirements

[PCC 17.13.020.A]

56. Permit-Wide

[PCC 17.13.020.A.5]

All reports and notifications shall be submitted in accordance with Condition 9 to the address in Condition 11.a.ii. Unless otherwise stated in the specific Conditions, all periodic reporting in this permit shall be aligned to reporting on an annual (due January 31st for Jan 1st – December 31st period), semi-annual (due January 31st for July 1st – December 31st period, and due by July 31st for January 1st – June 30th period), or calendar year quarter (due April 30th, July 31st, October 31st, and January 31st) basis. The first reports may not include a full 12, 6 or 3-month period, as applicable: [PCC 17.11.190.B, PCC 17.13.070 & PCC 17.24.050]

a. Periodic Reports

i. Annual Summary Reports of Required Monitoring

The Permittee shall submit an annual summary report of any required monitoring in this permit to include at a minimum the following:

- (a) EO Emission Cap Spreadsheet with monthly facility emissions rates showing compliance with the 12-month rolling total limitation in Condition 46.a.i. The spreadsheet shall be updated monthly within 20 days of the end of the month.
- (b) For APC 1 and 2, summary to include the monitored discharge rate(s) and the associated CEMS monitoring data collection requirements per Condition 53.a.ii.
- (c) For APC 3 – 8, summary to include the monitored discharge rate(s) and associated CEMS monitoring data collection requirements per Condition 53.a.iii., and monitoring required by Condition 46.b.ii(b) to include the following:
 - (i) Summary and duration of any malfunctions from requirements in this permit, to include APC unit(s) downtime or times taken out of service, as a percentage; and corrective actions necessary to restore APC or building management system parameters in accordance with the O & M plan.
- (d) Annual log of facility changes in accordance with Condition 9.d.ii.v:

ii. Annual NESHAP Subpart O reports in accordance with Condition 57.a.iii (Attachment 4).

b. Special Reporting and Notifications

The Permittee shall submit the following non-periodic reports, plans, and/or notifications:

- i. The O & M Plan in accordance with Condition 46.b.i to include:
 - (a) Fugitive EO Collection (capture) building management system report per Condition 46.b.ii(c).
 - (b) EO LDAR Program report per Condition 46.b.ii(d).
- ii. CEMS monitoring plan per Condition 55.a.i.
- iii. NESHAP Subpart O notifications and reports as applicable in accordance with Conditions 57.a.i., 57.a.ii., 57.e., and 57.f.
- iv. Other reports and notifications per Condition 9 (as applicable).

57. NESHAP Subpart O (See Attachment 4)

[40 CFR 63.366, PCC 17.13.020.A.5]

[**Federally Enforceable Conditions**]

The Permittee shall comply with all applicable provisions of the National Emission Standard for Hazardous Air Pollutants (NESHAP) as found in 40 CFR 63 Subpart O – “Ethylene Oxide Emission Standards for Sterilization Facilities,” for the operation of sterilization sources at the facility.

58. Special Monthly Report for Public Access

The Permittee shall submit a monthly summary report of the 12-month rolling “Facility Emissions Cap Spreadsheet” to the Control Officer. The Control Officer will provide a link, prominently and in a user friendly manner, on the Control Officer’s website to make such information available to the public.

ATTACHMENT 1: APPLICABLE REGULATIONS

40 CFR, Part 60 Standards of Performance for New Stationary Sources (PCC 17.16.490.A.1)

- Subpart A General Provisions.
- Subpart III NSPS for Compression Ignition Internal Combustion Engines
- Appendix A Test Methods.

40 CFR, Part 63, National Emissions Standards for Hazardous Air Pollutants (PCC 17.16.530.B.1 & 12)

- Subpart A General Provisions.
- Subpart O Source Category: Ethylene Oxide Emissions Standards for Sterilization Facilities

Pima County Code Title 17, Chapter 17.11 – General Provisions for Permits

- Article I – General Provisions**
 - 17.11.010 Statutory Authority.
 - 17.11.020 Planning, Constructing, or Operating Without a Permit.

- Article II – General Provisions for Stationary Source Permits**
 - 17.11.060 Permit Display or Posting.
 - 17.11.070 Public records – Confidentiality.
 - 17.11.090 Applicability – Classes of permits.
 - 17.11.100 Permits for State Delegated Emission Sources.
 - 17.11.110 Portable Sources.
 - 17.11.120 Material permit condition.
 - 17.11.150 Stack height limitation.
 - 17.11.160 Test methods and procedures.
 - 17.11.190 Permits containing synthetic emission limitations and standards.
 - 17.11.210 Performance tests.

Pima County Code Title 17, Chapter 17.13 – Permits and Permit Revisions for Class II and III Permits

- Article I – General Provisions**
 - 17.13.010 Application processing procedures.
 - 17.13.020 Permit contents.
 - 17.13.070 Establishment of an emissions cap for Class II and Class III permits.

- Article II – Permit Revisions, Renewals and Transfers for Class II and III Permits**
 - 17.13.100 Facility changes that require a permit revision.
 - 17.13.110 Procedures for certain changes that do not require a permit revision.
 - 17.13.120 Administrative amendments for Class II and Class III permits.
 - 17.13.130 Minor revisions.
 - 17.13.140 Significant revisions.
 - 17.13.150 Reopening, revocation, or termination.

- Article III – Emissions for Class II and Class III Sources**
 - 17.13.180 Annual Emissions inventory questionnaire.
 - 17.13.190 Excess emissions reporting requirements.

**Article IV - Public Participation for Class II and III permits
(Inclusive)**

Article V – Fees for Class II and Class III Sources

- 17.13.230 General Provisions.
- 17.13.240 Fees related to Class II and Class III permits.

Pima County Code Title 17, Chapter 17.14 – Activity Permits

Article I – General Provisions

- 17.14.060 Asbestos NESHAP activity permits.
- 17.14.080 Open burning permits.

Pima County Code Title 17, Chapter 17.16 – Emission Limiting Standards

Article I – General Provisions

- 17.16.010 Local rules and standards; Applicability of more than one standard.
- 17.16.020 Noncompliance with applicable standards.
- 17.16.030 Odor limiting standards.

Article II – Visible Emission Standards

- 17.16.040 Standards and applicability (includes NESHAP).
- 17.16.050 Visibility limiting standard.

**Article III – Emissions from Existing and Nonpoint Sources
(Inclusive)**

Article IV – New and Existing Stationary Source Performance Standards

- 17.16.130 Applicability
- 17.16.165 Standards of performance for fossil-fuel fired industrial and commercial equipment
- 17.16.490.A.1 NSPS – Subpart A – General Provisions
- 17.16.530.B.1 NESHAP – Subpart A – General Provisions
- 17.16.530.B.12 NESHAP – Subpart O – EO Emission Standards for Sterilization Facilities

Pima County Code Title 17, Chapter 17.20 – Emissions Source Testing and Monitoring

Article I – General Provisions

- 17.20.010 Source sampling, monitoring and testing

Article II – Concealment of Emissions

- 17.20.040 Concealment of emissions

Article III – Compliance Inspections

- 17.20.050 Compliance Inspections

Pima County Code Title 17, Chapter 17.24 – Emissions Source Recordkeeping and Reporting

Article I – Availability of Information

17.24.010 Confidentiality of trade secrets, sales data, and proprietary information

Article II – Recordkeeping Requirements

17.24.020 Recordkeeping for compliance determination

Article III – Reporting Requirements

17.24.050 Reporting as a permit requirement

17.24.060 Reporting for emission inventories

Article IV – Penalty for noncompliance (inclusive)

Pima County Code Title 17, Chapter 17.28 – Violations and Conditional Orders

Article I – Violations (inclusive)

Article II – Conditional Orders (inclusive)

Article III – Circumvention (inclusive)

ATTACHMENT 2: EQUIPMENT LIST

Equipment and Operations – for which emissions are allowed by this permit are as follows:

1) **Facility EO Emission Cap: 709 lb/yr monitored as a 12-month rolling total;**

[Ref. Cond 40, 46.a, 51.a, 53, 55, 56.a.i(a), 56.a.iii, 58]

2) **Table 1 – Sterilization Line Process Emissions Controls – (Phase 1 – ‘2023)**

[Ref. Conditions 40, 45, 46.a, 51.a, 52, 53.a.i & ii, 55.b, & 56.a.i(b), 56.a.ii, 56.b.iii, 57, 58]

Source ID Number	Description	MFR	Model	Serial Number Unique ID	Maximum Rated Capacity	Operating Parameters & Limitations	Fuels Used	Date of MFR	Date Installed
01	Sterilization Line 1; APC – 1, Cat-Ox Abatement System	LESNI	10,000	TBD ¹	225 tons EO/yr APC - 1&2	<p><u>Operating Parameter(s):</u></p> <ul style="list-style-type: none"> - EO usage monthly - EO emissions daily, monthly - Facility EO Emissions Cap 709lb as a 12-month rolling total Averages Recorded monthly [Cond 40, 46.a, 53.b.i, 53.b.ii] <p><u>NESHAP Subpart O STD:</u></p> <p>1 PPM, at the outlet</p> <p><u>Monitoring Data:</u> [Conditions 52.d.ii(a), 53.a.i & ii]</p> <p>Maintain raw emissions data and use 15-minute sub-hourly to determine average emissions for each day, and month for compliance with emission cap.</p> <p><u>APC CMS: Cat-Ox Temperature</u> [Cond 52.d.ii(a)]</p> <p>From 15-minute or shorter period temperature values, a data acquisition system (DAHS) for the temperature monitor shall compute and record a daily average oxidation temperature. Strip chart data shall be converted to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature.</p>	Natural Gas	TBD	TBD
	Sterilization Chamber 1 Aeration Room 1A Aeration Room 1B								
02	Sterilization Line 2; APC – 1, Cat-Ox Abatement System								
	Sterilization Chamber 2 Aeration Room 2A Aeration Room 2B								
03	Sterilization Line 3; APC – 1, Cat-Ox Abatement System								
	Sterilization Chamber 3 Aeration Room 3A Aeration Room 3B								
<p>Monitoring Method per Condition 46.a, 53.a.i and ii, and 55: CEMS and Periodic Performance RA tests (RATA & CGA’s) Continuous Monitoring System (CMS) – “LESNI Abatement system(s) – Catalyst Oxidation Temperature. [See Condition 52.d.ii(a)]</p>									

¹ TBD – To be Determined

3) Table 1 (continued) – Sterilization Line Process Emissions Controls – (Phase 2 – ‘2025)

[Ref. Conditions 40, 45, 46.a, 51.a, 52, 53.a.i & ii, 55.b, & 56.a.i(b), 56.a.ii, 56.b.iii, 57, 58]

Source ID Number	Description	MFR	Model	Serial Number Unique ID	Maximum Rated Capacity	Operating Parameters & Limitations	Fuels Used	Date of MFR	Date Installed
04	Sterilization Line 4; APC – 2, Cat-Ox Abatement System	LESNI	10,000	TBD ¹	225 tons EO/yr APC - 1&2	<p><u>Operating Parameter(s):</u></p> <ul style="list-style-type: none"> - EO usage monthly - EO emissions daily, monthly - Facility EO Emissions Cap <p>7091b as a 12-month rolling total</p> <p>Averages Recorded monthly [Cond 40, 46.a, 53.b.i, 53.b.ii]</p> <p><u>NESHAP Subpart O STD:</u></p> <p>1 PPM, at the outlet</p> <p><u>Monitoring Data:</u> [Conditions 52.d.ii(a), 53.a.i & ii]</p> <p>Maintain raw emissions data and use 15-minute sub-hourly to determine average emissions for each day, and month for compliance with emission cap.</p> <p><u>APC CMS: Cat-Ox Temperature</u> [Cond 52.d.ii(a)]</p> <p>From 15-minute or shorter period temperature values, a data acquisition system (DAHS) for the temperature monitor shall compute and record a daily average oxidation temperature. Strip chart data shall be converted to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature.</p>	Natural Gas	TBD	TBD
	Sterilization Chamber 4 Aeration Room 4A Aeration Room 4B								
05	Sterilization Line 5; APC – 2, Cat-Ox Abatement System								
	Sterilization Chamber 5 Aeration Room 5A Aeration Room 5B								
06	Sterilization Line 6; APC – 2, Cat-Ox Abatement System								
	Sterilization Chamber 6 Aeration Room 6A Aeration Room 6B								
<p>Monitoring Method per Condition 46.a, 53.a.i and ii, and 55: CEMS and Periodic Performance RA tests (RATA & CGA’s) Continuous Monitoring System (CMS) – “LESNI Abatement system(s) – Catalyst Oxidation Temperature. [See Condition 52.d.ii(a)]</p>									

TBD – To be Determined

4) Table 2 – Fugitive EO Emission Controls:

[Ref. Conditions 40, 46.a, 46.b, 51.a, 53.a.i, 53.a.iii, 53.b.ii(b), 53.b.iii, 55, 56.a.i.(c), 56.b.i]

Source ID Number	Description	MFR	Model	Serial Number/ Unique ID	Maximum Rated Capacity	Operating Parameters & Limits	Fuel Used	Date of MFR	Date Installed
07	APC-3 EO Dry Bed Scrubber(s): Gas Room Area – 1	Advanced Air Technologies	Safe Cell II DR490 (2 parallel beds, 2000 CFM each) System 2x	APC – 3 TBD	Fan: 4,000 CFM 3950 SCFM	<p>Operating Parameter(s):</p> <ul style="list-style-type: none"> - EO usage monthly - EO emissions daily, monthly - Facility EO Emissions Cap 12-month rolling total - Pressure Drop Avg. - Bldg Mgmt Sys. Parameters per O & M plan <p>Above Avgs Recorded monthly: [Cond 40, 46.a, 53.b.i, 53.b.ii]</p> <p>EO Discharge Limit: - 100 µg/m³ as a 1 hour average</p> <p>Monitored by CEMS [Cond 53.a.iii.(a)]</p>	N/A	TBD	TBD
08	APC-4 EO Dry Bed Scrubber(s): Sterilization Areas Chamber Rooms Area – 2	Advanced Air Technologies	Safe Cell II DR490 (2 parallel beds, 2000 CFM each) System 12x	APC – 4 TBD	Fan: 24,000 CFM 23, 701 SCFM	<p>Operating Parameter(s):</p> <ul style="list-style-type: none"> - EO usage monthly - EO emissions daily, monthly - Facility EO Emissions Cap 12-month rolling total - Pressure Drop Avg. - Bldg Mgmt Sys. Parameters per O & M plan <p>Above Avgs Recorded monthly: [Cond 40, 46.a, 53.b.i, 53.b.ii]</p> <p>EO Discharge Limit: - 100 µg/m³ as a 1 hour average</p> <p>Monitored by CEMS [Cond 53.a.iii.(a)]</p>	N/A	TBD	TBD

Attachment 2: Equipment List

Source ID Number	Description	MFR	Model	Serial Number/ Unique ID	Maximum Rated Capacity	Operating Parameters & Limitations	Fuel Used	Date of MFR	Date Installed
09	APC - 5 EO Dry Bed Scrubber(s): WIP Warehouse Area - 3	Advanced Air Technologies	Safe Cell II DR490 10X-Parallel Systems	TBD APC - 5	Fan: 20,000 CFM 19751 SCFM	<p>Operating Parameter(s):</p> <ul style="list-style-type: none"> - EO usage monthly - EO emissions daily, monthly - Facility EO Emissions Cap 12-month rolling total - Pressure Drop Avg. - Bldg Mgmt Sys. Parameters per O & M plan <p>Above Avgs Recorded monthly: [Cond 40, 46.a, 53.b.i, 53.b.ii]</p> <p>EO Discharge Limit: - 100 µg/m³ as a 1 hour average</p> <p>Monitored by CEMS [Cond 53.a.iii.(a)]</p>	N/A	TBD	TBD
10	APC - 6 EO Dry Bed Scrubber(s): WIP Warehouse Area - 3	Advanced Air Technologies	Safe Cell II DR490 10X-Parallel Systems	TBD APC - 6	Fan: 20,000 CFM 19751 SCFM	<p>Operating Parameter(s):</p> <ul style="list-style-type: none"> - EO usage monthly - EO emissions daily, monthly - Facility EO Emissions Cap 12-month rolling total - Pressure Drop Avg. - Bldg Mgmt Sys. Parameters per O & M plan <p>Above Avgs Recorded monthly: [Cond 40, 46.a, 53.b.i, 53.b.ii]</p> <p>EO Discharge Limit: - 100 µg/m³ as a 1 hour average</p> <p>Monitored by CEMS [Cond 53.a.iii.(a)]</p>	N/A	TBD	BD

Attachment 2: Equipment List

Source ID Number	Description	MFR	Model	Serial Number/ Unique ID	Maximum Rated Capacity	Operating Parameters & Limitations	Fuel Use d	Date of MFR	Date Installed
11	APC – 7 EO Dry Bed Scrubber(s): WIP Warehouse Area – 3	Advanced Air Technologies	Safe Cell II DR490 10X-Parallel Systems	TBD APC – 7	Fan: 20,000 CFM 19751 SCFM	<p>Operating Parameter(s):</p> <ul style="list-style-type: none"> - EO usage monthly - EO emissions daily, monthly - Facility EO Emissions Cap 12-month rolling total - Pressure Drop Avg. - Bldg Mgmt Sys. Parameters per O & M plan <p>Above Avgs Recorded monthly: [Cond 40, 46.a, 53.b.i, 53.b.ii]</p> <p>EO Discharge Limit: - 200 µg/m³ as a 1 hour average</p> <p>Monitored at least once each 15 minute period: [Cond 53.a.iii.(a)]</p>	N/A	TBD	TBD
12	APC – 8 EO Dry Bed Scrubber(s) WIP Warehouse Area – 3	Advanced Air Technologies	DR490 Systems 10X-Parallel Systems	TBD APC – 8	Fan: 20,000 CFM 19751 SCFM	<p>Operating Parameter(s):</p> <ul style="list-style-type: none"> - EO usage monthly - EO emissions daily, monthly - Facility EO Emissions Cap 12-month rolling total - Pressure Drop Avg. - Bldg Mgmt Sys. Parameters per O & M plan <p>Above Avgs Recorded monthly: [Cond 40, 46.a, 53.b.i, 53.b.ii]</p> <p>EO Discharge Limit: - 200 µg/m³ as a 1 hour average</p> <p>Monitored at least once each 15 minute period: [Cond 53.a.iii.(a)]</p>	N/A	TBD	TBD

5) ATO under GP 6205 – Fuel Burning Equipment

Equipment, operations, and activities for which emissions are allowed by the general permit are as follows:

§ 5 of the Permit – Boilers, Heaters, & Heaters:

Source ID	Description/ Location	MFR/ Model	Serial Number/ Unique ID	Maximum Rated Capacity	Date of MFR	Date Installed	Allowable Fuels and Annual Limits		Applicability ¹	
							Natural Gas	Fuel Oil	NSPS Subpart Dc	NESHAP Subpart JJJJJ
							(MMcf, hours, CF)	(Gallons, hours, CF)		
13	Boiler	TBD	TBD	8.17 MMBtu/hr	TBD	TBD	Unlimited	N/A	N/A	N/A
14	Boiler	TBD	TBD	8.17 MMBtu/hr	TBD	TBD	Unlimited	N/A	N/A	N/A
15	Boiler	TBD	TBD	8.17 MMBtu/hr	TBD	TBD	Unlimited	N/A	N/A	N/A

¹ The Permittee must submit a significant revision to revise this ATO and meet applicable NESHAP subpart JJJJJ work practices (tune-ups), notification, and reporting requirements for applicable boilers that switch to fuel oil use and become subject to Subpart JJJJJ in the oil firing subcategory as defined in 40 CFR 63.11237. The revision will be subject to a 5 day public comment period.

§ 6C – NSPS for CI ICE (Emergency Designated Engines):

Source ID	Description/ Location	MFR/ Model	Serial Number/ Unique ID	Maximum Rated Capacity	Date of MFR	Date Installed	Run Hour Limitation ¹	Allowable Fuels
16	Emergency Generator	TBD	TBD	980 hp	TBD	TBD	100 hours	Diesel
17	Fire Pump Engine	TBD	TBD	274 hp	TBD	TBD	100 hours	Diesel

¹ The run hours are limited to maintenance testing and readiness checks and non-emergency operation in accordance with the federal requirements. There is no limit on hours of operation during true emergencies.

§6C – Supplemental Requirements:

Equip. No.	Applicable NSPS Emission Standard	NO _x g/kw-hr (g/hp-hr)	NMHC g/kw-hr (g/hp-hr)	NMHC+NO _x g/kw-hr (g/hp-hr)	CO g/kw-hr (g/hp-hr)	PM g/kw-hr (g/hp-hr)	Certified Emission Life (term, date)
16	Emergency Engine 2007 and later model year	--	--	6.4 (4.8)	3.5 (2.6)	0.20 (0.15)	8,000 hours or 10 years, whichever comes first
17	Fire Pump Engine 2009 and later model year	--	--	4.0 (3.0)	3.5 (2.6)	0.20 (0.15)	8,000 hours or 10 years, whichever comes first

ATTACHMENT 3: GENERAL CONDITIONS**§ 1: General Provisions****1. Application, Permit Expiration and Renewal** [PCC 17.11.090.A, 17.13.010, 17.13.150, 17.13.160]

- a. The Permittee shall not commence construction of, operate, or make a modification to any source subject to regulation under Title 17 without obtaining a permit or permit revision from the Control Officer except as provided in Conditions 14.a.ii and 14.b or otherwise provided in Title 17 of the PCC.
- b. This permit is valid for a period of five years from the date of issuance and applies to a source requiring a Class II or III permit or permit revision. The Permittee may operate under the Conditions of this permit until 30 days after receipt of a notice of expiration, termination, or revocation of this permit.
- c. The Permittee or applicant shall submit timely applications according to the following:
 - i. For a source applying for a permit for the first time, a timely application is one that is submitted within 12 months after the source becomes subject to the permit program.
 - ii. For purposes of permit renewal, a timely application is one that is submitted at least 6 months, but not greater than 18 months prior to the date of permit expiration. As a courtesy, the Control Officer shall provide the Permittee a written notice of the expiration date of this permit stating the source must submit a renewal application.
 - iii. If this source becomes subject to a standard promulgated by the Administrator pursuant to § 112(d) of the Act (Hazardous Air Pollutants) then the Permittee shall, within twelve months of the date on which the standard is promulgated, submit an application for a permit revision demonstrating how the source will comply with such standard.
- d. The renewal of this permit shall be subject to the same procedural requirements, including any for public participation, affected states and administrator review, as applicable, that would apply during initial permit issuance. Permit expiration terminates the source's right to operate unless a timely application for renewal that is sufficient under ARS § 41-1064 has been submitted to the Control Officer. Any testing that is required for renewal shall be completed before the proposed permit is issued by the control officer. The control officer shall act on an application for a permit renewal within the same time frames as on an initial permit.
- e. Except as provided in Conditions 14.a.ii and 14.b, no source may operate after the time required to submit a timely and complete application to the Control Officer at the address in Condition 11.a.ii, except in compliance with a properly issued permit. However, an existing source that submits a timely and complete application for permit issuance, revision, or renewal, that is sufficient under ARS § 41-1064 is not in violation for failure to have a permit until the Control Officer takes final action on the application.

2. Construction or Modification and Operation [PCC 17.11.090.A & 17.13.080]

The Permittee shall construct or modify and shall operate affected emissions units and any air pollution controls (APC) in compliance with this permit, Title 17 of the PCC, and all other applicable federal air quality regulations; and in a manner consistent with representations made by the Permittee in an application or notice required by Conditions 1 and 14, to the extent the Control Officer relies upon these representations in approving a facility change, or issuing a permit revision, or renewal of this permit.

3. Location

[PCC 17.04.340.A .41, 128,129 & 229]

This permit authorizes the construction or modification and operation of the source only in the location described in this permit unless designated as a portable source pursuant to PCC 17.11.110. Should the Permittee choose to operate a portable source covered by this permit in another part of the State, outside Pima County, the Permittee shall, if required for such source, obtain an authorization or permit from the Director or Control Officer who has jurisdiction over the geographic area that includes the new location, and provide notice to that jurisdiction as provided in Condition 9.b.iv.(a)-(d) before commencing operation of such source.

4. Compliance with Permit Conditions

[PCC 17.13.020.A.7.a & b]

- a. The Permittee shall comply with all Conditions of this permit including all requirements of Arizona air quality statutes, and Title 17 of the Pima County Code. Compliance with the Conditions of this permit shall be deemed to be compliant with any applicable requirements identified in this permit as of the date of permit issuance. Any permit noncompliance is grounds for enforcement action; for terminating this permit, for revocation and reissuance, for revision; or for denial of a renewal application. In addition, noncompliance with any federally enforceable requirement constitutes a violation of the Clean Air Act (CAA).
- b. It shall not be a defense for a Permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the Conditions of this permit.

5. NAAQS & PSD Protection

[PCC 17.08.010 – 17.08.150]

The permitted source must not cause or contribute to a National Ambient Air Quality Standards (NAAQS) violation or, in an attainment area, must not cause or contribute to a Prevention of Significant Deterioration (PSD) increment violation.

6. Revision, Reopening, Revocation and Reissuance, or Termination for Cause

[PCC 17.13.020.A.7.c]

- a. This permit may be revised reopened, revoked and reissued, or terminated for cause. The filing of a request by the Permittee for a revision, revocation and reissuance, termination; or of a notification of planned changes or anticipated noncompliance does not stay any permit Condition.
- b. The permit shall be reopened and revised under any of the following circumstances:
 - i. Additional applicable requirements under the CAA become applicable to a major source. Such reopening shall only occur if there are three or more years remaining in the permit term. The reopening shall be completed not later than 18 months after promulgation of the applicable requirement. No such reopening is required if the effective date of the requirement is later than the date on which the permit is due to expire, unless the original permit or any of its terms and Conditions has been extended pursuant to Condition 1.d. Any permit reopening required pursuant to this paragraph shall comply with provisions in Condition 1.d for permit renewal and shall reset the five-year permit term.
 - ii. The Control Officer determines that the permit contains a material mistake or that inaccurate statements were made in establishing the emissions standards or other terms or Conditions of the permit.
 - iii. The Control Officer determines that the permit needs to be revised or revoked to assure compliance with the applicable requirements.

- c. Proceedings to reopen and issue a permit, including appeal of any final action relating to a permit reopening, shall follow the same procedures as apply to initial permit issuance and shall affect only those parts of the permit for which cause to reopen exists. Such re-openings shall be made as expeditiously as practicable. Permit re-openings for reasons other than those stated in Condition 6.b.i shall not result in the resetting of the five-year permit term.

7. Posting of Permit & Equipment Identification

[A.R.S. § 49-485, PCC 17.11.060]

- a. The Permittee shall retain a copy of this permit, and any applicable attachments onsite for review by the Control Officer. If it is not feasible to maintain a copy of the permit onsite the Permittee may request in writing, to maintain a copy of the permit at an alternate location. Upon written approval by the Control Officer, the Permittee must maintain a complete copy of the permit at the approved alternative location.
- b. When practicable the machine(s), equipment, device(s), article(s) or operation(s) for which the permit has been issued shall be affixed with a unique, clearly visible, and accessible ID in order to facilitate inspection and coordination with required monitoring records.

8. Fee Payment

[ARS 49-471.02, PCC 17.13.020.A.8 & PCC 17.13.240]

The Permittee shall pay fees to the Control Officer pursuant to PCC 17.13.240.

9. Reporting and Notifications

[PCC 17.13.020.A.5]

All notifications, reports, and applications required by this permit shall contain certification by a responsible official of truth, accuracy and completeness. The certification shall state that based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

[PCC 17.13.010.H]

The Permittee shall submit the following notifications and reports:

- a. Excess emission, permit deviation and emergency reports in accordance with Condition 11 below.
- b. Performance Test results in accordance with Condition 15.h below.
- c. Other reports and notifications as required by any condition in the Specific Conditions in this permit.
- d. Unless otherwise specified in the specific Conditions in this permit, the Permittee shall send the following reports and notifications, as applicable, to the Control Officer by mail, e-mail, facsimile, or hand delivery to the address in Condition 11.a.ii:
 - i. Notifications for NSPS Affected Facilities [40 CFR 60.7(a) & 60.19]

If the Permittee becomes subject to the NSPS standards in 40 CFR Part 60, unless otherwise specified in the applicable subpart, the Permittee shall submit an electronic notification as follows:

- (a) A notification of the date construction or reconstruction of an affected facility is commenced, postmarked no later than 30 days after such date. This requirement shall not apply in the case of mass-produced facilities which are purchased in completed form;
- (b) The date of initial startup under Condition 9.b.iii;

- (c) A notification of any physical or operational change to an existing facility which may increase the emission rate of any air pollutant to which a standard applies, unless that change is specifically exempted in 40 CFR Part 60. This notice shall be postmarked 60 days or as soon as practicable before the change is commenced and shall include information describing the precise nature of the change, present and proposed emission control systems, productive capacity of the facility before and after the change, and the expected completion date of the change. The Control Officer may request additional relevant information subsequent to this notice.
- ii. Notifications for NESHAP Affected Sources [PCC 17.13.010.C.3, 40 CFR 63.5(b)(4) & 40 CFR 63.9(b)]
 - (a) If this source becomes subject to a standard promulgated by the Administrator pursuant to § 112(d) of the CAA, then the Permittee shall, within 12 months of the date on which the standard is promulgated, submit an application for permit revision demonstrating how the source will comply with the standard.
 - (b) After the date of any relevant NESHAP standard in 40 CFR Part 63, if the Permittee constructs a new affected source (or makes a process change) or reconstructs an affected source that is subject to such standard, or reconstructs a source such that the source becomes subject to the standard, the Permittee must notify the Control Officer of the intended construction or reconstruction in accordance to the requirements in 40 CFR § 63.9(b) and Condition 14.b.i as applicable.
 - (c) Unless otherwise required in this permit, the Permittee shall provide the Control Officer a notification as required by 40 CFR § 63.9(j) of any change in the information already provided within 15 calendar days after the change.
 - iii. Startup Notifications [40 CFR 60.7(a), 40 63.9(b)(5), & PCC 17.13.240.C & D]

The Permittee shall notify the Control Officer of the date of startup for the following:

- (a) New sources or facilities authorized by this permit that have not been constructed or undergone initial startup. The Permittee must send a notification of the actual date of startup delivered within 15 calendar days after that date; and
 - (b) Inactive facilities paying a reduced fee that were shut-down the entire previous year in accordance with PCC 17.13.240.I.
- iv. Transfers of Permitted Portable Sources [PCC 17.11.110.E]

Before the transfer of a portable source permitted by the Control Officer to a new address in Pima County, or before the transfer of a portable source permitted by the Director to a location in the County currently operating under a separate air quality permit, the Permittee and/or owner or operator of such source shall notify the Control Officer at least 5 days before the transfer. The notification shall include the following information:

- (a) The new address and/or the latitude and longitude of the location where the portable source is to be transferred.
- (b) The source permit or ATO # and list of covered equipment to be transferred to the new location.
- (c) The expected duration of operation of the portable source at the new location.

- (d) A statement of the compliance status of the source with respect to the recordkeeping requirement in Condition 12.c including a certification of truth accuracy and completeness as provided in Condition 9.a.

v. Facility Changes [PCC 17.13.110]

The Permittee shall notify the Control Officer of facility changes requiring advance notification as provided in Condition 14.b.ii. The Permittee shall submit a copy of all other facility changes subject to logging requirements per Condition 14.b.i within 30 days of the anniversary of the permit issue date at the address in Condition 11.a.ii. If no changes were made at the source requiring logging, a statement to that effect shall be filed instead. The permittee may optionally send this notification on the dates and included with the facility-wide reports in Condition 48.d.

vi. Testing Notifications

The Permittee shall notify the Control Officer of any required testing per Condition 15.e.

vii. Emissions Inventory Reporting [PCC 17.13.180, 17.24.030 & ARS § 49-476.01]

- (a) When requested by the Control Officer, the Permittee shall complete and submit an annual emissions inventory questionnaire. The questionnaire is due by March 31st or ninety days after the Control Officer makes request and inventory form available, whichever occurs later, and shall include emission information for the previous calendar year. The questionnaire shall be on a form provided by or approved by the Control Officer and shall include the information required by PCC 17.13.180.

- (b) As an alternative, when provided, the Permittee may be requested to complete and submit an attached annual emission report to the address in Condition 11.a.ii.

viii. EPA Reporting

If the Permittee is required by this permit or an attachment to use the EPA Compliance and Emissions Data Reporting Interface (CEDRI) accessed through EPA's Central Data Exchange (CDX) (www.epa.gov/cdx) to submit information for permitted sources, the Permittee shall submit such reports and maintain such information for review per Condition 12.c.

e. Accident Prevention Requirements under the CAA (CAA Section 112(r))

Should this stationary source, as defined in 40 CFR 68.3 become subject to the accidental release prevention regulations in 40 CFR Part 68. In accordance with 40 CFR 68.10, the Permittee shall submit a risk management plan (RMP) by the specified date and shall certify compliance with the requirements of 40 CFR Part 68 and send such notification to the Control Officer.

10. Inspection and Entry

[ARS 41-1009][PCC 17.20.050]

Upon presentation of proper credentials, the Permittee must allow a representative of the reviewing authority to:

- a. Enter upon the premises where a permitted source is located or emissions-related activity is conducted or where records are required to be kept under the Conditions of the permit;
- b. Have access to and copy, at reasonable times, any records that are required to be kept under the Conditions of the permit;

- c. Inspect, during normal business hours or while the permitted source is in operation, any facilities, equipment (including monitoring and APC equipment), practices or operations regulated or required under the permit;
- d. Sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with the permit or other applicable requirements; and
- e. Record any inspection by use of written, electronic, magnetic and photographic media.

11. Excess Emissions, Permit Deviations, Emergency Reporting & Compliance Schedules

[PCC 17.13.020.A.5, PCC 17.13.020.C, PCC 17.11.190.B & PCC 17.13.190]

a. Excess Emissions Reporting

The Permittee shall report to the Control Officer any emissions in excess of the limits established by this permit. The report shall contain the information defined in § 2 and be in two parts as specified below:

- i. Notification by telephone or facsimile within 24 hours of the time the Permittee first learned of the occurrence of excess emission that includes all available information. The number to report excess emissions is **520-724-7400**. The facsimile number is **520-838-7432**.
- ii. Detailed written notification by submission of an excess emissions report within 72 hours of the notification under Condition 11.ai.

Send Notices to PDEQ 33 N. Stone Avenue, Suite 700, Tucson, Arizona 85701, or

E-mail for reports and other notifications: air.notices@pima.gov;

E-mail for permit applications, revisions, and facility changes: air.permits@pima.gov

b. Emergency Reporting

[PCC 17.13.020.C]

The Permittee shall, as soon as possible, telephone the Control Officer giving notice of the emergency and the Permittee shall submit a notice of the emergency to the Control Officer by certified mail, facsimile, hand delivery, or by e-mail within 2 working days of the time when emission limitations were exceeded due to the emergency. This notice shall contain a description of the emergency, any steps taken to mitigate emissions, and corrective action taken. An emergency constitutes an affirmative defense to an action brought for noncompliance with the technology-based emission limitations if the criteria described in § 2 are met.

c. Permit Deviation Reporting

[PCC 17.24.050]

The Permittee shall promptly report material deviations from permit requirements, including those attributable to upset conditions as defined in the permit, the probable cause of such deviations, and any corrective actions or preventive measures taken. Prompt reporting shall mean that the report was submitted to the Control Officer by certified mail, facsimile, E-mail (Air.Notices@pima.gov) or hand delivery to the address in Condition 11.a.ii within two working days of the time when emission limitations were exceeded due to an emergency or within two working days of the time when the Permittee first learned of the occurrence of a deviation from a permit requirement.

d. Compliance Schedule

[ARS 49-480.F.3 & 5]

For any excess emission or permit deviation that cannot be corrected within 72 hours, the Permittee is required to submit a compliance schedule to the Control Officer within 21 days of such occurrence. The compliance schedule shall include a schedule of remedial measures, including an enforceable sequence of actions with milestones, leading to compliance with permit terms or Conditions that have been violated.

12. Recordkeeping Requirements

[PCC 17.13.020.A.4]

a. Monitoring Information

The Permittee shall maintain records of monitoring information required by this permit. Records shall include at a minimum:

- i. The date, time, and permit Condition requiring the measurement, sampling, inspection, or procedure;
- ii. The name of the person conducting the measurement, sampling, inspection or procedure;
- iii. The particular piece of equipment, process, or area being monitored including a description of the operating conditions and monitoring procedure, technique, or methods used as applicable; and,
- iv. The results of the monitoring including any discrepancy or excess emissions. If there are any monitoring discrepancies or excess emissions, the records shall include the corrective actions taken.

b. Record Retention

[PCC 17.13.020.4.b]

The Permittee shall retain records of all required monitoring and support information for at least 5 years from the date of the monitoring sample, measurement, report, or application. Support information includes all calibration and maintenance records, and copies of all reports identified in Condition 9 required by this permit and any correspondence received from the Control Officer.

[Federally Enforceable – 2 year retention]

c. Record Maintenance for Compliance Determination

[PCC 17.24.020.A]

The Permittee shall maintain all permit required monitoring records and support information onsite and shall be considered in compliance by demonstrating that sufficient information on the equipment and facility operations is periodically collected, recorded, and maintained to assure that the compliance status of any permit Condition can be readily ascertained at any time.

13. Duty to Provide Information

[PCC 17.13.010.G & PCC 17.13.020.A.7.e]

- a. The Permittee shall furnish to the Control Officer, within a reasonable time, any information that the Control Officer may request in writing to determine whether cause exists for revising, revoking and reissuing, or terminating the permit or to determine compliance with the permit. Upon request, the Permittee shall also furnish to the Control Officer copies of records required to be kept by the permit.
- b. For information claimed to be confidential, the Permittee shall furnish a copy of such records to the Control Officer along with a claim of confidentiality in accordance with PCC 17.11.070.B.
- c. If the Permittee has failed to submit any relevant facts or if the Permittee has submitted incorrect information in the permit application, the Permittee shall, upon becoming aware of such failure or incorrect submittal, promptly submit such supplementary facts or corrected information.

14. Permit Amendment, Revision, and Facility Changes

[PCC 17.13.100, PCC 17.13.110, PCC 17.13.120, PCC 17.13.130 & PCC 17.13.140]

- a. The Permittee shall apply for a permit amendment or revision for changes which do not qualify for a facility change under Condition 14.b as follows:
 - i. Administrative Permit Amendment per PCC 17.13.120;
 - ii. Minor Permit Revision per PCC 17.13.130;

iii. Significant Permit Revision per PCC 17.13.140;

The applicability and requirements for the above permit actions are defined in the referenced regulations.

b. Facility Changes

- i. Except for a physical change or a change in the manner of operation of a source covered by this permit that requires a permit revision under PCC 17.13.100.A, or a facility change subject to logging or notice requirements under PCC 17.13.110, the Permittee shall not be required to revise this permit, provide advance notice, or log the facility or process change.
 - ii. For each facility change requiring advance notice, a written notice shall be sent to the address in Condition 11.a.ii and shall be received by the Control Officer the minimum amount of time in advance of the change. The written notice shall include: When the proposed change will occur, a description of the change, any change in emissions of regulated air pollutants, and any Conditions in this permit that are no longer applicable as a result of the change.
- c. No revision shall be required, under any approved economic incentives, marketable permits and other similar programs or processes for changes that are provided for in this permit.
- d. Notwithstanding Condition 14.b, the Control Officer may require the Permittee to revise a permit for any change that, when considered together with any other changes submitted by the Permittee over a 5 year term requires a revision or is required by Condition 14.b.i.

15. Testing Requirements

[PCC 17.11.160, PCC 17.11.210, PCC 17.20.010, PCC 17.20.040]

a. Incorporated Methods and Procedures

- i. Except as otherwise provided in this permit, the Permittee shall conduct performance tests (PT's) and reduce data in accordance with the test methods and procedures contained in the Arizona Testing Manual, 40 CFR 52 - Appendices D and E, 40 CFR 60 - Appendices A through F, 40 CFR 60.17, and 40 CFR 61 - Appendices B and C unless modified by the Control Officer pursuant to PCC 17.11.210.B or by the Director pursuant to A.A.C. R18-2-312.B.
- ii. Except as otherwise provided in this permit, the Permittee shall follow these general test methods and methodologies to determine compliance with emission limits:
 - (a) Opacity: The opacity of visible emissions shall be determined by EPA Test Method 9, Appendix A, 40 CFR Part 60 or by EPA approved Alternate Method ALT-082. [PCC 17.11.160.B]
 - (b) Fuel Sulfur Limitations: Documentation, such as tariff agreements or invoices or statements from the fuel supplier, showing the fuels delivered and verifying the fuel sulfur content is below applicable standards, shall be an acceptable means to demonstrate compliance with fuel sulfur limitations. If required or when requested by the Control Officer, the fuel sulfur content of fuels shall be determined using ASTM D129, D1266, D1552, D2622, D4294, D5453 or an equivalent for liquid fuels, and ASTM D1072, D3246, D4084, D4468, D4810, D6228, D6667, Gas Processors Association Standard 2377, or an equivalent for gaseous fuels.
 - (c) The heat content of solid fuel shall be determined according to ASTM Method D-3176-89, (Practice for Ultimate Analysis of Coal and Coke) and ASTM Method D-2015-91, (Test Method for Gross Calorific Value of Coal and Coke by the Adiabatic Bomb Calorimeter).
 - (d) Other testing and monitoring methods per PCC 17.11.210.H.

- iii. Nothing in Condition 15.a shall be construed to abrogate the Control Officer's authority to require the Permittee to conduct testing nor shall it be construed as to prevent the Permittee from utilizing measurements from emissions monitoring devices or techniques not designated as PT's as evidence of compliance with Condition 42.
 - iv. Except as otherwise provided in this permit, should the Permittee test to demonstrate compliance with this permit or Title 17 of the PCC, the Permittee shall contact the Control Officer at the phone number and address in Condition 11.a.ii for acceptable test methods and guidelines.
- b. Alternative Test Methods and Procedures: Except for ambient air monitoring or emissions testing of NSPS or NESHAP affected facilities and sources, the Permittee may submit an alternate and equivalent test method(s) listed in 40 CFR Subpart 60, Appendix A or is approved by the EPA as an alternative test method for approval by the Control Officer. (See EPA approved-alternative-test-methods for a listing of alternate test methods). Condition 55.c provides the currently approved methods and procedures approved by the Control Officer for compliance with the permit.
- c. Source Performance Testing: Unless otherwise stated in this permit, Sources required to conduct PT's shall do so within 60 days after the source has achieved the capability to operate at its maximum production rate on a sustained basis but no later than 180 days after initial startup of such sources. The Permittee shall conduct PT's as specified in this permit and at such other times as may be required by the Control Officer.
- d. Representative Operational Conditions: Performance tests shall be conducted under such conditions as the Control Officer shall specify to the plant operator based on representative performance of the source unless other conditions are required by the applicable test method or Conditions in this permit. With prior written approval from the Control Officer, testing may be performed at a lower rate. Operations during start-up, shutdown, and malfunction (as defined in PCC 17.04.340.A) shall not constitute representative operational conditions unless otherwise specified in the applicable requirement or this permit.
- e. Test Plan or Protocol
- Except as provided in Condition 15.a.ii, at least 14 calendar days prior to performing any required testing, the Permittee shall submit a test plan to the Control Officer, in accordance with PCC 17.11.210.D, and the Arizona Testing Manual. The test plan requirement may be waived by the Control Officer if the Permittee is retesting a source according to a previously submitted test plan. Notwithstanding the requirement to submit a test plan, the Permittee shall be required to notify the Control Officer of any dates of scheduled testing and any departures from the previously submitted plan, methods, or procedures provided in the permit.
- f. Performance Testing Facilities
- When required to do PT's, the Permittee shall provide or cause to be provided, PT facilities as follows:
[40 CFR 63.7(d)][40 CFR 60.8(e)]
- i. Sampling ports adequate for test methods applicable to the facility. This includes:
 - (a). Constructing the air pollution control system such that volumetric flow rates and pollutant emission rates can be accurately determined by applicable test methods and procedures; and
 - (b). Providing a stack or duct free cyclonic flow during PT's, as demonstrated by applicable test methods and procedures;
 - ii. Safe sampling platform(s);
 - iii. Safe access to sampling platform(s); and
 - iv. Utilities for sampling and testing equipment.
 - v. Any other facilities that the Control Officer deems necessary for safe and adequate testing of source.

g. Interpretation of Final Results

Unless otherwise specified in this permit, each PT shall consist of three separate runs using the applicable test method. Each run shall be conducted for the time and under the conditions specified in the applicable standard. For the purpose of determining compliance with an applicable standard, the arithmetic means of results of the three runs shall apply. In the event that a sample is accidentally lost or conditions occur in which one of the three runs is required to be discontinued because of forced shutdown, failure of an irreplaceable portion of the sample train, extreme meteorological conditions, or other circumstances beyond the Permittee’s control, compliance may, upon the Control Officer’s approval, be determined using the arithmetic mean of the results of the other two runs. If the Control Officer or the Control Officer’s designee is present, tests may only be stopped with the Control Officer’s or such designee’s approval. If the Control Officer or the Control Officer’s designee is not present, tests may only be stopped for good cause. Good cause includes: forced shutdown, failure of an irreplaceable portion of the sample train, extreme meteorological conditions, or other circumstances beyond the Permittee’s control. Termination of any test without good cause after the first run is commenced shall constitute a failure of the test. Supporting documentation, which demonstrates good cause, must be submitted.

h. Report of Final Test Results

Unless otherwise specified in this permit, a written report of the results of all PT’s required by this permit shall be submitted to the Control Officer within 30 days after the test is performed. The report shall be submitted in accordance with the Arizona Testing Manual and PCC 17.11.210.A. If additional time is needed to submit the results, the Permittee shall send a written request for an extension describing the circumstances and specifying the time needed to submit the report for approval by the control officer.

[AZ Testing Manual pg 8, 4 weeks ~ 30 days]

16. Property Rights [PCC 17.13.020.A.7.d]

The permit does not convey any property rights of any sort, or any exclusive privilege to the permit holder.

17. Liability

This permit does not release the Permittee from any liability for compliance with other applicable federal, state, and local environmental laws and regulations, including the CAA.

18. Severability Clause [PCC 17.13.020.A.6]

The provisions of this permit are severable. If any provision of this permit is held invalid, the remainder of this permit shall remain valid and in force.

19. Activity Permit Requirements (Asbestos, Open Burning, Fugitive Dust)

a. The Permittee shall not allow or commence demolition or renovation of any NESHAP facility, as defined in 40 CFR Part 61, Subpart M, National Emission Standards for Hazardous Air Pollutants – Asbestos, without first obtaining an activity permit from the Control Officer in accordance with PCC 17.14.060. Should this stationary source, pursuant to 40 CFR Part 61, Subpart M, become subject to asbestos regulations when conducting any renovation or demolition at this premises, then the Permittee or operator shall submit proper notification as described in 40 CFR Part 61, Subpart M and shall comply with all other applicable requirements of 40 CFR Part 61, Subpart M. The Permittee shall keep a record of all relevant paperwork on file.

[PCC 17.14.060 & 40 CFR 61, Subpart M]

b. The Permittee shall not ignite, cause to be ignited, permit to be ignited, allow or maintain any open outdoor fire without first obtaining an activity permit from the Control Officer or delegated authority unless exempted under PCC 17.14.080.C.

[PCC 17.14.080]

- c. The Permittee shall not conduct cause or allow land stripping, earthmoving, blasting, trenching or road construction without first obtaining an activity permit from the Control Officer in accordance with PCC 17.14.040.

20. Accident Prevention Requirements under the CAA (CAA Section 112(r))

Should this stationary source, as defined in 40 CFR 68.3 become subject to the accidental release prevention regulations in 40 CFR Part 68. In accordance with 40 CFR 68.10, the Permittee shall submit a risk management plan (RMP) by the specified date and shall certify compliance with the requirements of 40 CFR Part 68 and send such notification to the Control Officer and Administrator.

21. Stratospheric Ozone Depleting Substances.

The Permittee shall not use, sell, or offer for sale any fluid as a substitute material for use in any motor vehicle, residential, commercial, or industrial air conditioning system, refrigerator or freezer unit, or other cooling or heating device designed to use a chlorofluorocarbon (CFC) or hydrochlorofluorocarbon (HCFC) compound as a working fluid, unless such fluid has been approved for sale and such use by the Administrator. The Permittee shall keep a record of all paperwork relevant to the applicable requirements of 40 CFR 82, Subpart F onsite.

22. Credible Evidence

For the purpose of establishing whether the Permittee violated or is in violation of any requirement of this permit, nothing shall preclude the use, including the exclusive use, of any credible evidence or information relevant to whether a permitted source would have been in compliance with applicable requirements if the permittee had performed the appropriate performance or compliance test or procedure.

§ 2: Definitions

The following definitions shall have the meaning as defined in the CAA or Title 17 of the Pima County Code per PCC 17.04.340.A, unless otherwise defined in this permit. If a term is not defined, it shall be interpreted in accordance with normal business use. Terms with a single * asterisk AND highlighted (brown) are terms defined in NESHAP, Subpart A, § 63.2; Terms with a double asterisk **, and highlighted (green) are terms defined in NESHAP Subpart O.

Aeration room** means any vessel or room that is used to facilitate off-gassing of ethylene oxide at a sterilization facility.

Aeration room vent** means the point(s) through which the evacuation of ethylene oxide-laden air from an aeration room occurs.

Administrator* means the Administrator of the United States Environmental Protection Agency or his or her authorized representative (e.g., a State that has been delegated the authority to implement the provisions of this part).

Air Pollution or Air Pollutant (Title 17) means the presence in the outdoor atmosphere of one or more air contaminants or combination thereof, in sufficient quantities, which either alone or in connection with other substances, by reason of their concentration and duration are or tend to be injurious to human, plant, or animal life; or causes damage to property; or unreasonably interferes with the enjoyment of life or property of a substantial part of a community, or obscures visibility; or which in any way degrades the quality of the ambient air below the standards established by the board of supervisors.

Air pollutant (CAA) means any air pollution agent or combination of such agents, including any physical, chemical, biological, radioactive (including source material, special nuclear material, and byproduct material) substance or matter which is emitted into or otherwise enters the ambient air. Such term includes any precursors to the formation of any air pollutant to the extent the Administrator has identified such precursor or precursors for the particular purpose for which the term “air pollutant: is used.

Alternative requirements means the requirements, rules, permits, provisions, methods, or other enforceable mechanisms that a State submits for approval under this subpart or subpart A and, after approval, replaces the otherwise applicable Federal section 112 requirements, provisions, or methods. [as given in 40 CFR 63.90]

Area Source means any stationary source of hazardous air pollutants that is not a major source.

Baseline temperature** means a minimum temperature at the outlet from the catalyst bed of a catalytic oxidation control device or at the exhaust point from the combustion chamber of a thermal oxidation control device.

Chamber exhaust vent** means the point(s) through which ethylene oxide-laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes.

Calendar Day means from midnight to midnight of the following day.

Cause means with respect to the Control Officer's ability to deny an application or to revise, reopen, revoke or terminate this permit, for the following reasons: [PCC 17.13.150]

- a. The Control Officer determines that the permit needs to be revised or revoked to assure compliance with the applicable requirements;
- b. The Permittee has not been or is not in compliance with the terms and Conditions of this permit;
- c. The Control Officer determines that the emissions resulting from the construction, modification, and operation of a source significantly contributes to a NAAQS or a PSD increment violation, which are not adequately addressed by the requirements in this permit;
- d. The Permittee failed to disclose a material fact required by the application or the regulations applicable to the source for which the applicant had or should have had knowledge at the time the application was submitted.
- e. The Control Officer has reason to believe that the permit was obtained by fraud or misrepresentation;

Compliance date** means the date by which a source subject to the emissions standards in §63.362 is required to be in compliance with the standard.

Compliance schedule* means:

- a. In the case of an affected source that is in compliance with all applicable requirements established under 40 CFR Part 63, a statement that the source will continue to comply with such requirements; or

- b. In the case of an affected source that is required to comply with applicable requirements by a future date, a statement that the source will meet such requirements on a timely basis and, if required by an applicable requirement, a detailed schedule of the dates by which each step toward compliance will be reached; or
- c. In the case of an affected source not in compliance with all applicable requirements established under 40 CFR Part 63, a schedule of remedial measures, including an enforceable sequence of actions or operations with milestones and a schedule for the submission of certified progress reports, where applicable, leading to compliance with a relevant standard, limitation, prohibition, or any federally enforceable requirement established pursuant to section 112 of the Act for which the affected source is not in compliance. This compliance schedule shall resemble and be at least as stringent as that contained in any judicial consent decree or administrative order to which the source is subject. Any such schedule of compliance shall be supplemental to, and shall not sanction noncompliance with, the applicable requirements on which it is based.

Concealment with regard to an emission source shall include:

- a. The use of gaseous diluents to achieve compliance with an opacity standard or with a standard which is based on the concentration of a pollutant in the gasses discharged to the atmosphere.
- b. Operating in a piecemeal fashion to avoid compliance with a standard that would otherwise apply to the source on the basis of its size; and
- c. Operating in a manner, under conditions, or during such times that emissions cannot be observed.

Construction* means the on-site fabrication, erection, or installation of an affected source. Construction does not include the removal of all equipment comprising an affected source from an existing location and reinstallation of such equipment at a new location. The owner or operator of an existing affected source that is relocated may elect not to reinstall minor ancillary equipment including, but not limited to, piping, ductwork, and valves. However, removal and reinstallation of an affected source will be construed as reconstruction if it satisfies the criteria for reconstruction as defined in this section. The costs of replacing minor ancillary equipment must be considered in determining whether the existing affected source is reconstructed.

Control Officer means the director of Pima County Department of Environmental Quality who shall serve as the executive head of the Pima County air quality control district, or an authorized agent. Contact Information: Phone: (520) 724-7400; Website: [Pima County DEQ - air](#); E-mail: air.permits@pima.gov & air.notices@pima.gov

Continuous parameter monitoring system (CMS)* means the total equipment that may be required to meet the data acquisition and availability requirements of this permit, used to sample, condition (if applicable), analyze, and provide a record of process or control system parameters. For the purpose of this permit, the Permittee has chosen the option to use the catalyst oxidation temperature for purposes of the CMS parameter in accordance with Permit Condition 52.d.ii and for the CMS reporting requirements in [Condition 57.a.iii](#).

Continuous emission monitoring system (CEMS)* means the total equipment that may be required to meet the data acquisition and availability requirements of this permit, used to sample, condition (if applicable), analyze, and provide a record of emissions. For the purpose of determining compliance with this permit, wherever the term CEMS or continuous monitoring is used, this shall mean the system will continuously monitor the emissions stream and collect/record and sample the emission stream at least once every 15-minutes, any data obtained at lesser intervals shall be averaged, when possible. The average emissions rate will be calculated and recorded at 1-hour intervals, and reduced to 24-hour interval (daily) averages, and monthly emissions.

Dedicated CEMS For the purpose of this permit, a dedicated CEMS/DAHS shall mean the [CEMS](#) is equipped with dedicated sampling pump systems and heated sampling lines and sampling probes to each APC discharge point allowing for the collection and analysis of EO emission rates (EO concentration and flow data) from a central location without the requirement to be transported

Deviation** means any instance in which an affected source, subject to Subpart O or this permit, or an owner or operator of such a source:

- a. Fails to meet any requirement or obligation established by Subpart O or this permit including, but not limited to, any emission limitation (including any operating limit) or work practice standard;
- b. Fails to meet any term or condition that is adopted to implement an applicable requirement in Subpart O or that is included in the operating permit for any affected source required to obtain such a permit; or
- c. Fails to meet any emission limitation (including any operating limit) or work practice standard in Subpart O or this permit during startup, shutdown, or malfunction, regardless of whether or not such failure is permitted by Subpart O or this permit.

Effective date** means the date of promulgation in the Federal Register notice.

Director means the director of the Arizona Department of Environmental Quality. Contact Information: Phone: (602) 771-2285; ADEQ - Air Quality Division

Emergency means any situation arising from sudden and reasonably unforeseeable events beyond the control of the source, including acts of God, that require immediate corrective action to restore normal operation, and that cause the source to exceed a technology-based emission limitation under the permit, due to unavoidable increases in emissions attributable to the emergency. An emergency shall not include noncompliance to the extent caused by improperly designed equipment, lack of preventative maintenance, careless or improper operation, or operator error. [PCC 17.13.020.C]

- a. An emergency constitutes an affirmative defense to an action brought for noncompliance with the technology-based emission limitations if the following Conditions are met:
- b. The affirmative defense of emergency shall be demonstrated through properly signed, contemporaneous operating logs, or other relevant evidence that:
 - i. An emergency occurred and that the Permittee can identify the cause or causes of the emergency;
 - ii. At the time of the emergency, the permitted facility was being properly operated;
 - iii. During the period of the emergency the Permittee took all reasonable steps to minimize levels of emissions that exceeded the emissions standards or other requirements in the permit; and
 - iv. The Permittee submitted notice of the emergency as provided in Condition 16.b to the Control Officer by certified mail, facsimile, hand delivery, or by e-mail within two working days of the time when emission limitations were exceeded due to the emergency. This notice shall contain a description of the emergency, any steps taken to mitigate emissions, and corrective action taken.
- c. In any enforcement proceeding, the Permittee seeking to establish the occurrence of an emergency has the burden of proof.
- d. This provision is in addition to an emergency or upset provision contained in any applicable requirement.

Emission standard* means a national standard, limitation, prohibition, or other regulation promulgated in a subpart of this part pursuant to sections 112(d), 112(h), or 112(f) of the Act.

Emissions averaging is a way to comply with the emission limitations specified in a relevant standard, whereby an affected source, if allowed under a subpart of this part, may create emission credits by reducing emissions from specific points to a level below that required by the relevant standard, and those credits are used to offset emissions from points that are not controlled to the level required by the relevant standard.

Excess emissions report means:

- a. An excess emissions report shall contain the following information:
 - i. The identity of each stack or other emission point where the excess emissions occurred;
 - ii. The magnitude of the excess emissions expressed in the units of the applicable emission limitation and the operating data and calculations used in determining the magnitude of the excess emissions;
 - iii. The time and duration or expected duration of the excess emissions;
 - iv. The identity of the equipment from which the excess emissions emanated;
 - v. The nature and cause of the emissions;
 - vi. The steps taken, if the excess emissions were the result of a malfunction, to remedy the malfunction and the steps taken or planned to prevent the recurrence of the malfunctions;
 - vii. The steps that were or are being taken to limit the excess emissions; and
 - viii. If the source's permit contains procedures governing source operation during periods of startup or malfunction and the excess emissions resulted from startup or malfunction, a list of the steps taken to comply with the permit procedures.
- b. In the case of continuous or recurring excess emissions, the notification requirements of this Condition shall be satisfied if the source provides the required notification after excess emissions are first detected and includes in the notification an estimate of the time the excess emissions will continue. Excess emissions occurring after the estimated time period or changes in the nature of the emissions as originally reported shall require additional notification pursuant to Condition 11.a.

Excess emissions and continuous monitoring system performance report* is a report that must be submitted periodically by an affected source in order to provide data on its compliance with relevant emission limits, operating parameters, and the performance of its continuous parameter monitoring systems.

EPA means* the United States Environmental Protection Agency.

Equivalent emission limitation* means any maximum achievable control technology emission limitation or requirements which are applicable to a major source of hazardous air pollutants and are adopted by the Administrator (or a State with an approved permit program) on a case-by-case basis, pursuant to section 112(g) or (j) of the Act.

Facility Changes Requiring a Permit Revision means:

- a. Facility changes requiring the Permittee to apply for a permit revision per PCC 17.13.100:
 - i. A change that triggers a new applicable requirement not provided for in this permit or violates an existing applicable requirement or is a modification.
 - ii. Establishment of, or change in an emissions cap;
 - iii. A change that will require a case by case determination of an emission limitation or other standard, or a source specific determination of ambient impacts, or a visibility or increment analysis;
 - iv. A change that results in emissions that are subject to monitoring, recordkeeping or reporting under PCC 17.13.020.A.3, A.4, or A.5. If the emissions cannot be measured or otherwise adequately quantified by monitoring, recordkeeping, or reporting requirements already in the permit;
 - v. A change that will authorize or result in the burning of any fuel not currently authorized by the permit;
 - vi. Increasing operating or production rates, or operating hours over any limitations in the permit or establishing or revising a limit under PCC 17.11.190; or
 - vii. Replacement of an item of APC listed in the equipment list of this permit with one with one that does not have the same or better efficiency for reducing air pollutants.
 - viii. Relaxing monitoring, recordkeeping, or reporting requirements, except when the change results:
 - (a) From a change in an applicable requirement; or
 - (b) From removing equipment that results in a permanent decrease in actual emissions, if the source keeps on-site records of the change in a log that satisfies PCC 17.13.110.I.1 and I.2 and if the requirements that are relaxed are present in the permit solely for the equipment that was removed.
 - ix. A change that requires the source to obtain a Class I permit pursuant to PCC 17.11.090.A.

Facility Changes Subject to Logging or Notice Requirements means:

- a. Facility Changes Requiring Logging per PCC 17.13.110.B & I:
 - i. Changing process equipment, operating procedures, or any other physical change so long as the Permittee does not exceed any threshold listed in Condition 40, or violate any applicable Condition in this permit.
 - ii. Implementing an alternative operating scenario, including raw material changes.
 - iii. Engaging in any new insignificant activity that is not listed in Attachment 2 of the TSD.
 - iv. Replacing an item of APC equipment listed in the permit with an identical (same model, different serial number) item. The Control Officer may require verification of efficiency of the new equipment by PT's; and
 - v. A change that results in a decrease in actual emissions if the source wants to claim credit for the decrease in determining whether the source has a net emissions increase for any purpose. The logged information shall include a description of the change that will produce the decrease in actual emissions. A decrease that has not been logged is creditable only if the decrease is quantifiable, enforceable, and otherwise qualifies as a creditable decrease.
- b. Facility Changes Requiring Advance Notification per PCC 17.13.110.C & D:
 - i. The Permittee shall provide the Control Officer no less than 7 days advance notice before making a change in the method of operation that increases actual emissions by more than 10% of the major source threshold (10 tons per year) for any conventional pollutant but does not otherwise require a revision;
 - ii. The Permittee shall provide the Control Officer no less than 7 days advance notice for a change that amounts to reconstruction of the source or an affected facility: For purposes of this requirement, reconstruction of a source or an affected facility shall be presumed if the fixed capital cost of the new components exceeds fifty percent of the fixed capital cost of a comparable entirely new source and the changes to the components have occurred over the twelve consecutive months beginning with commencement of construction;
 - iii. The Permittee shall provide the Control Officer no less than 7 days advance notice before replacing a listed item of APC equipment with one that is not identical but that is substantially similar and has the same or better pollutant reduction efficiency;

- iv. The Permittee shall provide the Control Officer no less than 30 days advance notice for a change that would trigger an applicable requirement that already exists in the permit, unless otherwise provided in the Conditions of this permit.
- v. The Permittee shall provide the Control Officer no less than 30 days advance notice before replacing a listed item of APC equipment with one that is not substantially similar but that has the same or better pollutant removal efficiency.
- vi. The Permittee shall provide the Control Officer no less than 30 days advance notice for a change that will result in the emissions of a new regulated air pollutant above an applicable regulatory threshold but that does not trigger a new applicable requirement for that source category. For purposes of this requirement, an applicable regulatory threshold for a regulated air pollutant shall be a significant increase in the net emissions of pollutants listed in PCC 17.04.340.A or ten percent of the applicable major source threshold for that pollutant, whichever is less.

Federally enforceable* means all limitations and conditions that are enforceable by the Administrator and citizens under the Act or that are enforceable under other statutes administered by the Administrator. Examples of federally enforceable limitations and conditions include, but are not limited to:

- a. Emission standards, alternative emission standards, alternative emission limitations, and equivalent emission limitations established pursuant to section 112 of the Act as amended in 1990;
- b. New source performance standards established pursuant to section 111 of the Act, and emission standards established pursuant to section 112 of the Act before it was amended in 1990;
- c. All terms and conditions in a title V permit, including any provisions that limit a source's potential to emit, unless expressly designated as not federally enforceable;
- d. Limitations and conditions that are part of an approved State Implementation Plan (SIP) or a Federal Implementation Plan (FIP);
- e. Limitations and conditions that are part of a Federal construction permit issued under 40 CFR 52.21 or any construction permit issued under regulations approved by the EPA in accordance with 40 CFR part 51;
- f. Limitations and conditions that are part of an operating permit where the permit and the permitting program pursuant to which it was issued meet all of the following criteria:
 - i. The operating permit program has been submitted to and approved by EPA into a State implementation plan (SIP) under section 110 of the CAA;
 - ii. The SIP imposes a legal obligation that operating permit holders adhere to the terms and limitations of such permits and provides that permits which do not conform to the operating permit program requirements and the requirements of EPA's underlying regulations may be deemed not "federally enforceable" by EPA;
 - iii. The operating permit program requires that all emission limitations, controls, and other requirements imposed by such permits will be at least as stringent as any other applicable limitations and requirements contained in the SIP or enforceable under the SIP, and that the program may not issue permits that waive, or make less stringent, any limitations or requirements contained in or issued pursuant to the SIP, or that are otherwise "federally enforceable";
 - iv. The limitations, controls, and requirements in the permit in question are permanent, quantifiable, and otherwise enforceable as a practical matter; and
 - v. The permit in question was issued only after adequate and timely notice and opportunity for comment for EPA and the public.
- g. Limitations and conditions in a State rule or program that has been approved by the EPA under subpart E of this part for the purposes of implementing and enforcing section 112; and
- h. Individual consent agreements that the EPA has legal authority to create.

Federally enforceable means:

- a. The requirements of the New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants contained in Articles VI and Article VII of Chapter 17.16.
- b. The requirements of such other state or county rules or regulations approved by the administrator, including the requirements of approved state and county operating and new source review permit programs that have been approved by the administrator.
- c. The requirements of any applicable implementation plan.
- d. Emissions limitations, controls, and other requirements, and any associated monitoring, recordkeeping and reporting requirements, which are entered into voluntarily by a source pursuant to PCC 17.11.190.

Force majeure* means, for purposes of §63.7, an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents the owner or operator from complying with the regulatory requirement to conduct PT's within the specified timeframe despite the affected facility's best efforts to fulfill the obligation. Examples of such events are acts of nature, acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility.

Fixed capital cost* means the capital needed to provide all the depreciable components of an existing source.

Fugitive emissions* means those emissions from a stationary source that could not reasonably pass through a stack, chimney, vent, or other functionally equivalent opening. Under section 112 of the Act, all fugitive emissions are to be considered in determining whether a stationary source is a major source.

Good engineering practice (GEP) stack height means a stack height meeting the requirements described in PCC 17.11.150.

HAP containing material means a material that contains any volatile or nonvolatile HAP that is an Occupational Safety and Health Administration (OSHA)-defined carcinogen as specified in 29 CFR 1910.1200(d) at a concentration greater than 0.1 percent by mass, or greater than 1.0 percent by mass for any other HAP compound. For the purpose of determining whether materials used contain the HAP compounds, the Permittee may rely on formulation data provided by the manufacturer or supplier, such as the safety data sheet (SDS), as long as it represents HAP compound in the material that is present at 0.1 percent by mass or more for OSHA-defined carcinogens as specified in 29 CFR 1910.1200(d) and at 1.0 percent by mass or more for other HAP compounds.

Hazardous Air Pollutant (HAP) means a pollutant listed in § 112(b) of the CAA.

High Sulfur Oil means fuel oil containing 0.90 percent or more by weight of sulfur.

Intermediate change to monitoring means a modification to federally required monitoring involving “proven technology” (generally accepted by the scientific community as equivalent or better) that is applied on a site-specific basis and that may have the potential to decrease the stringency of the associated emission limitation or standard. Though site-specific, an intermediate change may set a national precedent for a source category and may ultimately result in a revision to the federally required monitoring. Examples of intermediate changes to monitoring include, but are not limited to:

- (1) Use of a continuous emission monitoring system (CEMS) in lieu of a parameter monitoring approach;
- (2) Decreased frequency for non-continuous parameter monitoring or physical inspections;
- (3) Changes to quality control requirements for parameter monitoring; and
- (4) Use of an electronic data reduction system in lieu of manual data reduction.

[as given in 40 CFR 63.90]

Intermediate change to test method means a within-method modification to a federally enforceable test method involving “proven technology” (generally accepted by the scientific community as equivalent or better) that is applied on a site-specific basis and that may have the potential to decrease the stringency of the associated emission limitation or standard. Though site-specific, an intermediate change may set a national precedent for a source category and may ultimately result in a revision to the federally enforceable test method. In order to be approved, an intermediate change must be validated according to EPA Method 301 (Part 63, Appendix A) to demonstrate that it provides equal or improved accuracy and precision. Examples of intermediate changes to a test method include, but are not limited to:

- (1) Modifications to a test method's sampling procedure including substitution of sampling equipment that has been demonstrated for a particular sample matrix, and use of a different impinger absorbing solution;
- (2) Changes in sample recovery procedures and analytical techniques, such as changes to sample holding times and use of a different analytical finish with proven capability for the analyte of interest; and
- (3) “Combining” a federally required method with another proven method for application to processes emitting multiple pollutants.

[as given in 40 CFR 63.90]

Initial startup date** (For the purpose of this permit, See Condition 52.a).

Invalid CEMS Data: For the purpose of this permit, invalid CEMS data periods (also referred to as un-certified data periods, or data collected when the CEMS is out-of-control), that require substitution of the PTE values in Condition 53.a.iv(b), or uncontrolled PTE values on page 21 of TSD (if excess emissions, due to malfunction), shall generally be implied to mean the following periods, excluding any period of routine downtime allowance for up to 1 hour per day (for calibration and maintenance, wherein the previous hourly emission average may be substituted for that hour). For reference as a guideline for clarification of any un-defined conditions and procedures please refer to “40 CFR Part 75 Emissions Monitoring Policy Manual”:

- 1) Any monitoring hour during operation wherein the CEMS system fails to obtain an ethylene oxide concentration in at least two of the four 15-minute sub-hourly periods; and

- 2) Any operating hours during an operating day wherein the CEMS has not completed a daily calibration;
- 3) Any hourly time periods following a failed quarterly QA test (relative accuracy (RA) test), wherein and until such time that the unit is able to pass such test, and again achieve “certified status” by meeting all of the following criteria:
 - (a) Completion of a daily calibration of the CEMS concentration analyzer to the Zero and Hi-Span daily Calibration standards;
 - (b) Passing a 7-day calibration drift test (normally conducted prior to an RA test (RATA or Cylinder Gas Audit (CGA)) but may be conducted immediately following such test); and
 - (c) Passing a CGA or RATA test;
- 4) All other periods of monitored CEMS EO concentrations shall be considered conditionally valid data for use in calculating the hourly, daily, monthly and 12-month rolling total facility emissions cap, and shall be validated (certified) upon completion of the next passing quarterly RA test (RATA or CGA) whether regularly scheduled or otherwise, unless any such findings are disputed by the Control Officer. Data exempted for routine downtime periods for up to 1 hour per operating day for calibration and maintenance, may be substituted with the previous hourly average.

Notwithstanding such periods above defined as invalid, or conditionally invalid CEMS data (and flagged by the CEMS system and/or demarcated in the monitoring records) that may require appropriate data substitution with the correct PTE values, all such data and other valid data (as applicable) shall then be considered conditionally valid and used towards determining and calculating the facility emissions for the previous quarter. All conditionally valid concentration data in the previous quarter shall be determined and certified as valid CEMS data upon completion and passing of the next scheduled quarterly RA test, unless the Control Officer has reason to question or dispute such finding. Any such disputed periods may be certified or invalidated on a case-by case basis upon review and investigation of the findings.

With respect to the flow monitoring data logged by the DAHS used to calculate emissions by the CEMS, all flow data shall be conditionally valid until the next scheduled RATA, and bias adjusted following such RATA (if required per Condition 55.b.ii) to adjust and/or re-certify the monitored emissions for the previous year. Any missing or invalidated flow data due to malfunction, shall be substituted with the maximum flow rate listed in the equipment list and shall count against the data collection requirements of the CEMS/DAHS system in Conditions 53.a.ii.(b) and 53.a.iii.(c) but shall not be required bias adjustment unless findings from a RATA determine such a need to adjust the maximum expected flows upward.

Major change to test method means a modification to a federally enforceable test method that uses “unproven technology or procedures” (not generally accepted by the scientific community) or is an entirely new method (sometimes necessary when the required test method is unsuitable). A major change to a test method may be site-specific, or may apply to one or more sources or source categories, and will almost always set a national precedent. In order to be approved, a major change must be validated according to EPA Method 301 (part 63, appendix A). Examples of major changes to a test method include, but are not limited to:

- (1) Use of an unproven analytical finish;
- (2) Use of a method developed to fill a test method gap;
- (3) Use of a new test method developed to apply to a control technology not contemplated in the applicable regulation; and
- (4) Combining two or more sampling/analytical methods (at least one unproven) into one for application to processes emitting multiple pollutants.

[as given in 40 CFR 63.90]

Major change to monitoring means a modification to federally required monitoring that uses “unproven technology or procedures” (not generally accepted by the scientific community) or is an entirely new method (sometimes necessary when the required monitoring is unsuitable). A major change to monitoring may be site-specific or may apply to one or more source categories and will almost always set a national precedent. Examples of major changes to monitoring include, but are not limited to:

- (1) Use of a new monitoring approach developed to apply to a control technology not contemplated in the applicable regulation;
- (2) Use of a predictive emission monitoring system (PEMS) in place of a required continuous emission monitoring system (CEMS);

- (3) Use of alternative calibration procedures that do not involve calibration gases or test cells;
- (4) Use of an analytical technology that differs from that specified by a performance specification;
- (5) Decreased monitoring frequency for a continuous emission monitoring system, continuous opacity monitoring system, predictive emission monitoring system, or continuous parameter monitoring system;
- (6) Decreased monitoring frequency for a leak detection and repair program; and
- (7) Use of alternative averaging times for reporting purposes. [as given in 40 CFR 63.90]

Major source* means any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants, unless the Administrator establishes a lesser quantity, or in the case of radionuclides, different criteria from those specified in this sentence.

Major source threshold means the lowest applicable emissions rate for a pollutant that would cause the source to be a major source as defined in PCC 17.04.340.A.128.

Malfunction* means any sudden, infrequent, and not reasonably preventable failure of air pollution control and monitoring equipment, process equipment, or a process to operate in a normal or usual manner which causes, or has the potential to cause, the emission limitations in an applicable standard to be exceeded. Failures that are caused in part by poor maintenance or careless operation are not malfunctions.

Malfunction means any sudden and unavoidable failure of APC equipment, process equipment or a process to operate in a normal manner, but does not include failures that are caused by poor maintenance, careless operations or any other upset condition or equipment breakdown that could have been prevented by the exercise of reasonable care.

- a. The Permittee has an affirmative defense for excess emissions due to malfunction, startup, and shutdown as provided in PCC 17.13.200.
- b. For NESHAP sources listed in this permit: [40 CFR 63.6(e)]
During a period of startup, shutdown, or malfunction, the general duty to minimize emissions requires that the owner or operator reduce emissions from the affected source to the greatest extent which is consistent with safety and good air pollution control practices. The general duty to minimize emissions during a period of startup, shutdown, or malfunction does not require the owner or operator to achieve emission levels that would be required by the applicable standard at other times if this is not consistent with safety and good air pollution control practices, nor does it require the owner or operator to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved.

Manifolding emissions* means combining ethylene oxide emissions from two or more different vent types for the purpose of controlling these emissions with a single control device.

Material permit condition means a condition that satisfies all of the following:

- a. The condition is in a permit or permit revision issued by the Control Officer.
- b. The condition is identified within the permit as a material permit condition.
- c. The condition is one of the following:
 - i. An enforceable emission standard imposed to avoid classification as a major modification or major source or to avoid triggering any other applicable requirement.
 - ii. A requirement to install, operate or maintain a maximum achievable control technology or hazardous air pollutant reasonably available control technology required pursuant to the requirements of A.R.S. § 49-426.06.
 - iii. A requirement for the installation or certification of a monitoring device.
 - iv. A requirement for the installation of APC equipment.
 - v. A requirement for the operation of APC equipment.
 - vi. Any opacity standard required by Section 111 (Standards of Performance for New Stationary Sources) or Title I, Part C or D (Air Pollution Prevention and Control) of the Act.
- d. Violation of the condition is not covered by subsections A through F, or H through J of A.R.S. § 49-464 or subsections A through F, or H through J of A.R.S. § 49-514.

Maximum ethylene glycol concentration** means any concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device established during a PT when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

Maximum liquor tank level means any level of scrubber liquor in the acid-water scrubber liquor recirculation tank established during a PT when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

Maximum liquor tank level** means any level of scrubber liquor in the acid-water scrubber liquor recirculation tank established during a PT when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

Modification or modify means a physical change in or change in the method of operation of a source that increases the emissions of any regulated air pollutant emitted by such source by more than any relevant de minimis amount or that results in the emission of any regulated air pollutant not previously emitted by more than such de minimis amount. An increase in emissions at a minor source shall be determined by comparing the source's potential to emit before and after the modification. The following exemptions apply:

- a. A physical or operational change does not include routine maintenance, repair or replacement.
- b. An increase in the hours of operation or if the production rate is not considered an operational change unless such increase is prohibited under any federally enforceable permit condition or other permit condition that is enforceable as a practical matter.
- c. A change in ownership at a source is not considered a modification.

Minor change to monitoring means: [as given in 40 CFR 63.90]

(1) A modification to federally required monitoring that:

- (i) Does not decrease the stringency of the compliance and enforcement measures for the relevant standard;
- (ii) Has no national significance (e.g., does not affect implementation of the applicable regulation for other affected sources, does not set a national precedent, and individually does not result in a revision to the monitoring requirements); and
- (iii) Is site-specific, made to reflect or accommodate the operational characteristics, physical constraints, or safety concerns of an affected source.

(2) Examples of minor changes to monitoring include, but are not limited to:

- (i) Modifications to a sampling procedure, such as use of an improved sample conditioning system to reduce maintenance requirements;
- (ii) Increased monitoring frequency; and
- (iii) Modification of the environmental shelter to moderate temperature fluctuation and thus protect the analytical instrumentation.

Minor change to test method means: [as given in 40 CFR 63.90]

(1) A modification to a federally enforceable test method that:

- (i) Does not decrease the stringency of the emission limitation or standard;
- (ii) Has no national significance (e.g., does not affect implementation of the applicable regulation for other affected sources, does not set a national precedent, and individually does not result in a revision to the test method); and
- (iii) Is site-specific, made to reflect or accommodate the operational characteristics, physical constraints, or safety concerns of an affected source.

(2) Examples of minor changes to a test method include, but are not limited to:

- (i) Field adjustments in a test method's sampling procedure, such as a modified sampling traverse or location to avoid interference from an obstruction in the stack, increasing the sampling time or volume, use of additional impingers for a high moisture situation, accepting particulate emission results for a test run that was conducted with a lower than specified temperature, substitution of a material in the sampling train that has been demonstrated to be more inert for the sample matrix; and
- (ii) Changes in recovery and analytical techniques such as a change in quality control/quality assurance requirements needed to adjust for analysis of a certain sample matrix.

Monitoring* means the collection and use of measurement data or other information to control the operation of a process or pollution control device or to verify a work practice standard relative to assuring compliance with applicable requirements. Monitoring is composed of four elements:

- a. **Indicator(s) of performance***—the parameter or parameters you measure or observe for demonstrating proper operation of the pollution control measures or compliance with the applicable emissions limitation or standard. Indicators of performance may include direct or predicted emissions measurements (including opacity), operational parametric values that correspond to process or control device (and capture system) efficiencies or emissions rates, and recorded findings of inspection of work practice activities, materials tracking, or design characteristics. Indicators may be expressed as a single maximum or minimum value, a function of process variables (for example, within a range of pressure drops), a particular operational or work practice status (for example, a damper position, completion of a waste recovery task, materials tracking), or an interdependency between two or among more than two variables.

- b. **Measurement techniques***—the means by which you gather and record information of or about the indicators of performance. The components of the measurement technique include the detector type, location and installation specifications, inspection procedures, and quality assurance and quality control measures. Examples of measurement techniques include continuous emission monitoring systems, continuous opacity monitoring systems, continuous parametric monitoring systems, and manual inspections that include making records of process conditions or work practices.
- c. **Monitoring frequency***—the number of times you obtain and record monitoring data over a specified time interval. Examples of monitoring frequencies include at least four points equally spaced for each hour for continuous emissions or parametric monitoring systems, at least every 10 seconds for continuous opacity monitoring systems, and at least once per operating day (or week, month, etc.) for work practice or design inspections.
- d. **Averaging time***—the period over which you average and use data to verify proper operation of the pollution control approach or compliance with the emissions limitation or standard. Examples of averaging time include a 3-hour average in units of the emissions limitation, a 30-day rolling average emissions value, a daily average of a control device operational parametric range, and an instantaneous alarm.

New affected source* means the collection of equipment, activities, or both within a single contiguous area and under common control that is included in a section 112(c) source category or subcategory that is subject to a section 112(d) or other relevant standard for new sources. This definition of “new affected source,” and the criteria to be utilized in implementing it, shall apply to each section 112(d) standard for which the initial proposed rule is signed by the Administrator after June 30, 2002. Each relevant standard will define the term “new affected source,” which will be the same as the “affected source” unless a different collection is warranted based on consideration of factors including:

- a. Emission reduction impacts of controlling individual sources versus groups of sources;
- b. Cost effectiveness of controlling individual equipment;
- c. Flexibility to accommodate common control strategies;
- d. Cost/benefits of emissions averaging;
- e. Incentives for pollution prevention;
- f. Feasibility and cost of controlling processes that share common equipment (e.g., product recovery devices);
- g. Feasibility and cost of monitoring; and

New source* means any affected source the construction or reconstruction of which is commenced after the Administrator first proposes a relevant emission standard under this part establishing an emission standard applicable to such source.

Nonpoint Source means, for the purpose of this permit, any source of air contaminants which due to a lack of an identifiable emission point or plume cannot be considered a point source, including fugitive dust producing activities. In applying this criteria, such items as air curtain destructors, heater planers, and conveyor transfer points shall be considered to have identifiable plumes.

Operation means any physical or chemical action resulting in the change in location, form, physical properties or chemical character of a material.

Owner or operator* means any person who owns, leases, operates, controls, or supervises a stationary source.

Oxidation temperature means** the temperature at the outlet point of a catalytic oxidation unit control device or at the exhaust point from the combustion chamber for a thermal oxidation unit control device.

Performance audit* means a procedure to analyze blind samples, the content of which is known by the Administrator, simultaneously with the analysis of PT samples in order to provide a measure of test data quality.

Performance evaluation* means the conduct of relative accuracy testing, calibration error testing, and other measurements used in validating the continuous monitoring system data.

Performance test (PT)* means the collection of data resulting from the execution of a test method (usually three emission test runs) used to demonstrate compliance with a relevant emission standard as specified in the PT section of the relevant standard.

Permitting authority* means:

- a. The State air pollution control agency, local agency, other State agency, or other agency authorized by the Administrator to carry out a permit program under 40 CFR Part 70; or
- b. The Administrator, in the case of EPA-implemented permit programs under Title V of the Act (42 U.S.C. 7661).

Pollution Prevention* means source reduction as defined under the Pollution Prevention Act (42 U.S.C. 13101-13109). The definition is as follows:

- a. Source reduction is any practice that:
 - i. Reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling, treatment, or disposal; and
 - ii. Reduces the hazards to public health and the environment associated with the release of such substances, pollutants, or contaminants.
- b. The term source reduction includes equipment or technology modifications, process or procedure modifications, reformulation or redesign of products, substitution of raw materials, and improvements in housekeeping, maintenance, training, or inventory control.
- c. The term source reduction does not include any practice that alters the physical, chemical, or biological characteristics or the volume of a hazardous substance, pollutant, or contaminant through a process or activity which itself is not integral to and necessary for the production of a product or the providing of a service.

Portable Source means any building, structure, facility or installation subject to regulation under ARS § 49-426 that emits or may emit any air pollutant and is capable of being operated at more than one location.

Potential to emit* means the maximum capacity of a stationary source to emit a pollutant under its physical and operational design. Any physical or operational limitation on the capacity of the stationary source to emit a pollutant, including air pollution control equipment and restrictions on hours of operation or on the type or amount of material combusted, stored, or processed, shall be treated as part of its design if the limitation or the effect it would have on emissions is enforceable.

Reconstruction, unless otherwise defined in a relevant standard*, means the replacement of components of an affected or a previously nonaffected source to such an extent that:

- a. The fixed capital cost of the new components exceeds 50 percent of the fixed capital cost that would be required to construct a comparable new source; and
- b. It is technologically and economically feasible for the reconstructed source to meet the relevant standard(s) established by the Administrator (or a State) pursuant to section 112 of the Act. Upon reconstruction, an affected source, or a stationary source that becomes an affected source, is subject to relevant standards for new sources, including compliance dates, irrespective of any change in emissions of hazardous air pollutants from that source.

Regulated air pollutant means any of the following:

- a. Any conventional pollutant defined in ARS § 49-401.01 – means any pollutant for which the Administrator has promulgated a primary or secondary national ambient air quality standard.
- b. Nitrogen Oxides and volatile organic compounds
- c. Any air contaminant that is subject to a standards contained in Chapter 17.16 or Article VI
- d. Any Class I or II substance listed in Section 602 of the Act (Listing of Class I and Class II Substances)

Regulation promulgation schedule* means the schedule for the promulgation of emission standards under this part, established by the Administrator pursuant to section 112(e) of the Act and published in the Federal Register.

Relevant standard* means:

- a. An emission standard;
- b. An alternative emission standard;
- c. An alternative emission limitation; or
- d. An equivalent emission limitation established pursuant to section 112 of the Act that applies to the collection of equipment, activities, or both regulated by such standard or limitation. A relevant standard may include or consist of a design, equipment, work practice, or operational requirement, or other measure, process, method, system, or technique (including prohibition of emissions) that the Administrator (or a State) establishes for new or existing sources to which such standard or limitation applies. Every relevant standard established pursuant to section 112 of the Act includes subpart A of this part, as provided by §63.1(a)(4), and all applicable appendices of this part or of other parts of this chapter that are referenced in that standard.

Responsible official* means one of the following:

- a. For a corporation: A president, secretary, treasurer, or vice president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or a duly authorized representative of such person if the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities and either:
 - i. The facilities employ more than 250 persons or have gross annual sales or expenditures exceeding \$25 million (in second quarter 1980 dollars); or

- ii. The delegation of authority to such representative is approved in advance by the Administrator.
- b. For a partnership or sole proprietorship: a general partner or the proprietor, respectively.
- c. For a municipality, State, Federal, or other public agency: either a principal executive officer or ranking elected official. For the purposes of this part, a principal executive officer of a Federal agency includes the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency (e.g., a Regional Administrator of the EPA).
- d. For affected sources applying for or subject to a title V permit: “responsible official” shall have the same meaning as defined in part 70 or Federal title V regulations in this chapter (42 U.S.C. 7661), whichever is applicable.

Run* means one of a series of emission or other measurements needed to determine emissions for a representative operating period or cycle as specified in this part.

Shutdown means* the cessation of operation of an affected source or portion of an affected source for any purpose.

Source means any building, structure, facility or installation that may cause or contribute to air pollution or the use of which may eliminate, reduce or control the emission of air pollution. Source may also mean the Permittee or facility as a facility-wide entity.

Source(s) using less than 1 ton** means source(s) using less than 907 kg (1 ton) of ethylene oxide within all consecutive 12-month periods after December 6, 1996.

Source(s) using 1 ton** means source(s) using 907 kg (1 ton) or more of ethylene oxide within any consecutive 12-month period after December 6, 1996.

Source(s) using 1 to 10 tons** means source(s) using 907 kg (1 ton) or more of ethylene oxide in any consecutive 12-month period but less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

Source(s) using less than 10 tons** means source(s) using less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

Source(s) using 10 tons** means source(s) using 9,070 kg (10 tons) or more of ethylene oxide in any consecutive 12-month period after December 6, 1996.

Source at a Performance Track member facility* means a major or area source located at a facility which has been accepted by EPA for membership in the Performance Track Program (as described at www.epa.gov/PerformanceTrack) and is still a member of the Program. The Performance Track Program is a voluntary program that encourages continuous environmental improvement through the use of environmental management systems, local community outreach, and measurable results.

State* means all non-Federal authorities, including local agencies, interstate associations, and State-wide programs, that have delegated authority to implement: (1) The provisions of 40 CFR Part 63 and/or (2) the permit program established under 40 CFR Part 70. The term State shall have its conventional meaning where clear from the context.

Stationary source means any building, structure, facility or installation subject to regulation that emits or may emit any air pollutant.

Sterilization chamber** means any enclosed vessel or room that is filled with ethylene oxide gas, or an ethylene oxide/inert gas mixture, for the purpose of sterilizing and/or fumigating at a sterilization facility.

Sterilization chamber vent means the point (prior to the vacuum pump) through which the evacuation of ethylene oxide from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.

Sterilization chamber vent** means the point (prior to the vacuum pump) through which the evacuation of ethylene oxide from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.

Sterilization facility** means any stationary source where ethylene oxide is used in the sterilization or fumigation of materials.

Sterilization operation** means any time when ethylene oxide is removed from the sterilization chamber through the sterilization chamber vent or the chamber exhaust vent or when ethylene oxide is removed from the aeration room through the aeration room vent.

Thermal oxidizer** means all combustion devices except flares.

VOC - Volatile Organic Compounds means any compound of carbon, excluding carbon monoxide (CO), carbon dioxide (CO₂), carbonic acid, metallic carbides, or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions. This includes any organic compound other than those in the definition in PCC 17.04.340.A.250, which have been determined to have negligible photochemical reactivity.

VOC Containing means a material that contains two percent by weight or more VOC as determined by the manufacturer’s safety data sheet (SDS) or technical product data sheet, or ASTM 2369, or methods set forth in 40 CFR 60, Appendix A. For the purpose of determining whether materials used contain the VOC compounds, the Permittee may rely on formulation data provided by the manufacturer or supplier, such as the safety data sheet (SDS).

Volatile Organic Liquid (VOL) means any organic liquid which can emit volatile organic compounds (as defined in 40 CFR 51.100) into the atmosphere.

VHAP Containing means a HAP containing material that contains volatile HAP constituents.

Working day* means any day on which Federal Government offices (or State government offices for a State that has obtained delegation under section 112(l)) are open for normal business. Saturdays, Sundays, and official Federal (or where delegated, State) holidays are not working days.

Work practice standard means any design, equipment, work practice, or operational standard, or combination thereof that is promulgated pursuant to § 112(h) of the Clean Air Act.

ATTACHMENT 4: NESHAP Subpart O - Specific Conditions (§§ 4, 5, 5a, 5b, and 5c)

§ 4: Emission Limitations and Standards

[PCC 17.13.020.A.2]
[Federally Enforceable Conditions]

45. NESHAP Subpart O

The NESHAP Subpart O provisions below apply to affected commercial stationary sterilization sources pursuant to the application on file with the Control Officer and as listed in Table 1 of the equipment list.

- a. The Permittee must comply with the requirements in 40 CFR Part 63, Subpart A according to the applicability in Table 1 of 40 CFR 63.360. [40 CFR 63.360(a)]

- b. **Standards** [40 CFR 63.362]

The Permittee shall comply with the following emission standard immediately upon startup of the source. The emission limitations in Conditions 45.b.i below apply during sterilization operations. The emission limitations do not apply during periods of malfunction. [40 CFR 63.362(a) and (b)]

- i. The combined emissions from the sterilization chamber and aeration chamber vent shall be reduced by at least 99 percent or a maximum of 1 PPM_v whichever is **more** stringent at the outlet of the LESNI cat-ox abatement system(s) in the equipment list. [40 CFR 63.362(c)&(d)]

§ 5: Compliance Determination

[PCC 17.13.020.A.3, 4, & 5]
[Federally Enforceable Conditions]

§ 5a: Monitoring and Recordkeeping

[PCC 17.13.020.A.3 & 4]

52. The Permittee shall conduct an initial performance test (PT) using the procedures listed 40 CFR 63.7 according to Table 1 of 40 CFR 63.360 and the following listed procedures and test methods: [40 CFR 63.363(a)]

- a. **Performance Testing** [40 CFR 63.363(a)(2)]

The Permittee shall complete the PT of each sterilization source subject to Condition 45 within 180 days after startup. Each sterilization line will include one sterilization chamber and two aeration rooms.

[Note: For the purpose of this permit, initial startup shall be defined as “the date when a source subject to the emission standards in Condition 45.b.i begins a sterilization process. The sterilization process shall be further defined to initiate in the chambers when EO is used after the chamber validation process has been completed per FDA requirements. In no event shall the facility use more than 2 tons of EO for validation purposes without triggering startup, unless the Permittee submits a notification requesting an extension of the PT and stated reasons necessary for any startup delays.]

- b. **Initial Compliance & Work Practices** [40 CFR 63.363(b)]

- i. The following procedures shall be used to determine initial compliance with the emission limits in Condition 45.b.i, and to establish operating limits for the LESNI[®] ethylene oxide abatement system listed in the equipment list (Source ID's 01-06):

- (a) The Permittee shall determine the efficiency of the sterilization line control device using the test methods and procedures in Condition 54. [40 CFR 63.363(b)(1)]

- (b) The operating limit shall consist of the recommended minimum oxidation temperature provided by the manufacturer for an operating limit. [40 CFR 63.363(b)(3)]

(c) The Permittee shall comply with one of the following work practices: [40 CFR 63.363(b)(4)]

- (i) Once per year after the initial compliance test, conduct a PT during routine operations, i.e., with product in the chamber using the procedures described in Condition 54.b or 54.c as appropriate. If the percent efficiency is less than 99 percent or the concentration in the control device outlet exceeds 1 PPM, restore the catalyst as soon as practicable but no later than 180 days after conducting the PT; or
- (ii) Once per year after the initial compliance test, analyze ethylene oxide concentration data from Condition 54.c.i or a continuous emission monitoring system (CEMS) and restore the catalyst as soon as practicable but no later than 180 days after data analysis; or
- (iii) Every 5 years, beginning 5 years after the initial compliance test, replace the catalyst bed with new catalyst material.

ii. The Permittee shall use either of the following procedures to determine initial compliance with the emission limits in Condition 45.b.i, for the affected LESNI[®] ethylene oxide abatement system discharge points: [40 CFR 63.363(c)]

- (a) Determine the concentration of ethylene oxide into the atmosphere (after any control device used to comply with Condition 45.b.i) using the methods in Condition 54.c.i; or
- (b) Determine the efficiency of the control device used to comply with Condition 45.b.i using the test methods and procedures in Condition 54.d.ii.

c. **Continuous Compliance** [40 CFR 63.363(f)]

The facility must demonstrate continuous compliance with each operating limit and work practice standard required in Condition 52.b, except during periods of startup, shutdown, and malfunction, according to the methods in Condition 52.d.

d. **Monitoring Requirements** [40 CFR 63.364]

[Continuous Monitoring System (CMS) – “LESNI Abatement system(s) – Thermal Oxidation Temp (DAHS) or CEMS]

i. The Permittee shall monitor the parameters specified in Condition 52.d as stated below. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system. [40 CFR 63.364(a)(1 & 2)]

ii. The Permittee shall either comply with Condition 52.d.ii(b) or 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 the temperature monitor described in Condition 52.d.ii(a). Monitoring is required only when the oxidation unit is operated. From 15-minute or shorter period temperature values, a data acquisition system (DAHS) for the temperature monitor shall compute and record a daily average oxidation temperature. Strip chart data shall be converted to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature. [40 CFR 63.364(c)]

- (a) The Permittee shall install, calibrate, operate, and maintain a temperature monitor accurate to within ± 5.6 °C (± 10 °F) to measure the oxidation temperature. The Permittee shall verify the accuracy of the temperature monitor twice each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or 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. As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards). [40 CFR 63.364(c)(4)]

- (b) Measure and record once per hour the ethylene oxide concentration at the outlet to the atmosphere after any control device according to the procedures specified in Condition 54.c.i. The owner or operator shall compute and record a 24-hour average daily. The owner or operator will install, calibrate, operate, and maintain a monitor consistent with the requirements of performance specification (PS) 8 or 9 in 40 CFR part 60, appendix B, to measure ethylene oxide. The daily calibration requirements of Section 7.2 of PS-9 or Section 13.1 of PS-8 are required only on days when ethylene oxide emissions are vented to the control device. [40 CFR 63.364(e)]
- iii. The Permittee shall comply with the monitoring requirements in 40 CFR 63.8 according to the applicability in Table 1 of 40 CFR 63.360 and as specified in 40 CFR 63.364. [40 CFR 63.364(a)(1)]
 - (a) Operation and maintenance of continuous monitoring system (CMS). [40 CFR 63.8(c)]
 - (i) When the emissions from two or more affected sources are combined before being released to the atmosphere, the Permittee may install an applicable CMS for each emission stream or for the combined emissions streams, provided the monitoring is sufficient to demonstrate compliance with the relevant standard.
 - (ii) The Permittee must develop a written startup, shutdown, and malfunction plan for each CMS. [40 CFR 63.8.(c)(1)(iii)]
 - (iii) All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system. [40 CFR 63.364(a)(2)]
 - (iv) All CMS must be installed such that representative measures of emissions or process parameters from the affected source are obtained. The owner or operator must ensure the read out (that portion of the CMS that provides a visual display or record), or other indication of operation, from any CMS required for compliance with the emission standard is readily accessible on site for operational control or inspection by the operator of the equipment. [40 CFR 63.8.(c)(2)]
 - (v) All CMS shall be installed, operational, and the data verified as specified herein either prior to or in conjunction with conducting PT's under 40 CFR 63.7. Verification of operational status shall, at a minimum, include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system. [40 CFR 63.8.(c)(3)]
- iv. Monitoring data recorded during periods of unavoidable CMS breakdowns, out-of-control periods, repairs, maintenance periods, calibration checks, and zero (low-level) and high-level adjustments must not be included in any data average computed under this part. The data averages must include any data recorded during periods of monitor breakdown or malfunction.
- v. As applicable, and any other time the Control Officer may require under section 114 of the CAA, the Permittee shall conduct a performance evaluation of the CMS.

- e. **Recordkeeping Requirements** [40 CFR 63.367]
- i. The Permittee shall comply with the recordkeeping requirements in 40 CFR 63.10(b) and (c) as provided below. All records required to be maintained (including all reports and notifications) shall be maintained in such a manner that they can be readily accessed and are suitable for inspection in accordance with Condition 12. The files shall be retained for 5 years with at least 2 years of records retained on-site, the remaining 3 years of data may be retained off-site. The Permittee may maintain files on microfilm, on computer files, or on microfiche. [40 CFR 63.10(b)(1)]
- (a) The Permittee shall maintain relevant records for such source of: [40 CFR 63.10(b)(2)]
- (i) The occurrence and duration of each malfunction of operation (i.e., process equipment) of the required air pollution control and monitoring equipment; [40 CFR 63.10(b)(2)(ii)]
- (ii) Each period during which a CMS is malfunctioning or inoperative (including out-of-control periods); [40 CFR 63.10(b)(2)(vi)]
- (iii) All required measurements needed to demonstrate compliance with a relevant standard (including, but not limited to, 15-minute averages of CMS data, raw PT measurements, and raw performance evaluation measurements, that support data that the source is required to report); [40 CFR 63.10(b)(2)(vii)]
- (A) The Control Officer, upon notification to the source, may require the owner or operator to maintain all measurements as required by Condition 52.e.i(a)(iii), if the Control Officer determines these records are required to more accurately assess the compliance status of the affected source.
- (iv) All results of performance tests, CMS performance evaluations, and opacity and visible emission observations (as applicable);
- (v) All measurements as may be necessary to determine the conditions of performance tests and performance evaluations;
- (vi) All results of PT's, and when requested by the Control Officer, CMS performance evaluations;
- (vii) All measurements as may be necessary to determine the conditions of PT's, and when requested by the Control Officer, performance evaluations;
- (viii) All CMS calibration checks
- (ix) All adjustments and maintenance performed on CMS;
- (x) Any information demonstrating whether a source is meeting the requirements for a waiver of recordkeeping or reporting requirements, if the source has been granted a waiver under 40 CFR 63.10(f);
- (xi) All documentation supporting initial notifications and notifications of compliance status under 40 CFR 63.9.
- (b) Additional recordkeeping requirements for CMS: In addition to complying with the requirements specified in Condition 52.e.i, the Permittee shall maintain the following records:
- (i) All required CMS measurements (including monitoring data recorded during unavoidable CMS breakdowns and out-of-control periods);

- (ii) The date and time identifying each period during which the CMS was inoperative except for zero (low-level) and high-level checks;
 - (iii) The specific identification (i.e., the date and time of commencement and completion) of each time period of excess emissions and parameter monitoring exceedances, that occurs during periods other than startups, shutdowns, and malfunctions;
 - (iv) The nature and cause of any malfunction (if known);
 - (v) The corrective action taken or preventive measures adopted;
 - (vi) The nature of the repairs or adjustments to the CMS that was inoperative or out of control;
 - (vii) The total process operating time during the reporting period; and
 - (viii) When requested by the Control Officer, procedures that are part of a quality control program to be developed and implemented for the CMS under 40 CFR 63.8(d).
- ii. The Permittee shall maintain records of the compliance test, data analysis, and if catalyst is replaced, proof of replacement.

§5b Testing

[PCC 17.13.020.A.3]

[Federally Enforceable Conditions]

54. NESHAP Subpart O

[40 CFR 63.365, PCC 17.13.020.A.3]

- a. **Performance Testing:** The Permittee shall comply with the PT requirements in 40 CFR 63.7 in addition to the requirements herein. [40 CFR 63.365(a)]
- b. **Measuring Efficiency of the Sterilization Chamber Vent:** California Air Resources Board (CARB) Method 431, or approved CEMS (See Condition 54.c.i), or the following procedures shall be used to determine the efficiency of all types of control devices used to comply with Condition 52.b.ii. [40 CFR 63.365(b)]
- i. **First Evacuation of the Sterilization Chamber:** These procedures shall be performed on an empty sterilization chamber, charged with a typical amount of ethylene oxide, for the duration of the first evacuation under normal operating conditions (i.e., sterilization pressure and temperature).

(a) The amount of ethylene oxide loaded into the sterilizer (W_c) shall be determined by either:

- (i) Weighing the ethylene oxide gas cylinder(s) used to charge the sterilizer before and after charging. Record these weights to the nearest 45 g (0.1 lb). Multiply the total mass of gas charged by the weight percent ethylene oxide present in the gas;
- (ii) Installing calibrated rotameters at the sterilizer inlet and measuring flow rate and duration of sterilizer charge. Use the following equation to convert flow rate to weight of ethylene oxide:

$$W_c = F_v \times t \times \%EO_v \times \left(\frac{MW}{SV}\right) \quad \text{where:}$$

W_c = weight of ethylene oxide charged, g (lb)

F_v = volumetric flow rate, liters per minute (L/min) corrected to 20 °C and 101.325 kilopascals (kPa) (scf per minute (scfm) corrected to 68 °F and 1 atmosphere of pressure (atm)); the flowrate must be constant during time (t)

t = time, min

$\%EO_v$ = volume fraction ethylene oxide

SV = standard volume, 24.05 liters per mole (L/mole) = 22.414 L/mole ideal gas law constant corrected to 20 °C and 101.325 kPa (385.32 scf per mole (scf/mole) = 359 scf/mole ideal gas law constant corrected to 68 °F and 1 atm).

MW = molecular weight of ethylene oxide, 44.05 grams per gram-mole (g/g-mole) (44.05 pounds per pound-mole (lb/lb-mole)), or

- (iii) Calculating the mass based on the conditions of the chamber immediately after it has been charged using the following equation:

$$W_c = \left(\frac{MW \times \%EO_v \times P \times V}{R \times T}\right)$$

where:

P = chamber pressure, kPa (psia)

V = chamber volume, liters (L) (ft³)

R = gas constant, 8.313 L·kPa/g-mole·(10.73 psia·ft³/mole·°R)

T = temperature, K (°R)

Note: If the ethylene oxide concentration is in weight percent, use the following equation to calculate mole fraction:

$$\%EO_v = \frac{W_{EO}}{W_{EO} + \left(W_x \frac{MW}{MW_x}\right)}$$

where:

W_{EO} = weight percent of ethylene oxide

W_x = weight percent of compound in the balance of the mixture

MW_x = molecular weight of compound in the balance gas mixture

- (b) The residual mass of ethylene oxide in the sterilizer shall be determined by recording the chamber temperature, pressure, and volume after the completion of the first evacuation and using the following equation:

$$W_r = \left(\frac{MW_x \%EO_v \times P \times V}{R \times T} \right)$$

where:

W_r = weight of ethylene oxide remaining in chamber (after the first evacuation), in g (lb)

- (c) Calculate the total mass of ethylene oxide at the inlet to the control device (W_i) by subtracting the residual mass (W_r) calculated in Condition 54.b.i.(b) from the charged weight (W_c) calculated in Condition 54.b.i.(a).

- (d) The mass of ethylene oxide emitted from the control device outlet (W_o) shall be calculated by continuously monitoring the flow rate and concentration using the following procedure.

- (i) Measure the flow rate through the control device exhaust continuously during the first evacuation using the procedure found in 40 CFR part 60, appendix A, Test Methods 2, 2A, 2C, or 2D, as appropriate. (Method 2D (using orifice plates or Rootstypemeters) is recommended for measuring flow rates from sterilizer control devices.) Record the flow rate at 1-minute intervals throughout the test cycle, taking the first reading within 15 seconds after time zero. Time zero is defined as the moment when the pressure in the sterilizer is released. Correct the flow to standard conditions (20 °C and 101.325 kPa (68 °F and 1 atm)) and determine the flow rate for the run as outlined in the test methods listed in Condition 54.b.

- (A) Test Method 18 or 25A, 40 CFR part 60, appendix A (hereafter referred to as Method 18 or 25A, respectively), shall be used to measure the concentration of ethylene oxide.

1. Prepare a graph of volumetric flow rate versus time corresponding to the period of the run cycle. Integrate the area under the curve to determine the volume.

2. Calculate the mass of ethylene oxide by using the following equation:

$$W_o = C \times V \times \left(\frac{MW}{SV} \right) \times \frac{1}{10^6}$$

Where:

W_o = Mass of ethylene oxide, g (lb)

C = concentration of ethylene oxide in ppmv

V = volume of gas exiting the control device corrected to standard conditions, L(ft³)

$1/10^6$ = correction factor $L_{EO}/10^6 L_{TOTAL\ GAS}$ (ft³_{EO}/10⁶ ft³_{TOTAL\ GAS})

3. Calculate the efficiency by the equation in Condition 54.b.i.(e) below.

- (e) Determine control device efficiency (% Eff) using the following equation:

$$\%Eff = \frac{W_i}{W_o} \times 100$$

where:

$\% Eff$ = percent efficiency; W_i = mass flow rate into the control device

W_o = mass flow rate out of the control device

- (f) Repeat the procedures in Conditions 54.b.i.(a) through 54.b.i.(e) three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.
- c. **Concentration Determination:** The following procedures shall be used to determine the ethylene oxide concentration. [40 CFR 63.365(c)]
- i. **Initial Compliance:** For determining the ethylene oxide concentration required in Condition 52.b.ii, and 52.d.ii(b) the procedures outlined in Method 18 or Method 25A (40 CFR part 60, appendix A) or as otherwise specified in this paragraph shall be used. A performance test consists of three 1-hour runs. If using an instrumental method to determine concentration, calibrate and report the instrument results using ethylene oxide as the calibration gas. The arithmetic average of the ethylene oxide concentration of the three test runs shall determine the overall outlet ethylene oxide concentration from the control device. Instrumental procedures approved by the Control Officer for measuring concentrations at lower detection levels may also be used such as FTIR (Fourier Transform Infrared) spectroscopy such as EPA Method 320 and ALT 142. In lieu of the performance test, the permittee may also use an installed CEMS in accordance with Condition 55.b.
- d. **Efficiency Determination at the Aeration Room Vent (not manifolded):** The following procedures shall be used to determine the efficiency of a control device used to comply with Condition 45.b.i. [40 CFR 63.365(d)]
- i. Determine the concentration of ethylene oxide at the inlet and outlet of the control device using the procedures in Condition 45.c.i.
- ii. Determine control device efficiency (% Eff) using the following equation:
$$\% \text{Eff} = \frac{W_i - W_o}{W_i} \times 100$$
where:
% Eff = percent efficiency
 W_i = mass flow rate into the control device
 W_o = mass flow rate out of the control device
- iii. Repeat the procedures in Conditions 54.d.i and 54.d.ii three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.
- e. If the Permittee of a sterilization facility seeks to demonstrate compliance with the requirements of Condition 52 or 53.a, with a monitoring device or procedure other than a gas chromatograph or a flame ionization analyzer, the Permittee shall provide to the Control Officer and Administrator information describing the operation of the monitoring device or procedure and the parameter(s) that would demonstrate continuous compliance with each operating limit. The Control Officer and Administrator may request further information and will specify appropriate test methods and procedures. [40 CFR 63.365(h)]

§ 5c: Reporting Requirements

[PCC 17.13.020.A.5]

[Federally Enforceable Conditions]

57. NESHAP Subpart O

[40 CFR 63.366, PCC 17.13.020.A.5]

The Permittee shall fulfill all reporting requirements in 40 CFR 63.10(a), (d), (e), and (f) of Subpart A, according to the applicability in Table 1 of 40 CFR 63.360. These reports will be made available to the Control Officer at the address in Condition 11.a.ii, and the Administrator in Condition 9.d.viii and 40 CFR 63.13 as applicable according to the following provisions. If the Permittee has been granted an extension of compliance under 40 CFR 63, Subpart D or 40 CFR 63.6(i), or if the Permittee has been granted a waiver by the Administrator under 40 CFR 63.10(f), the following reports, except for any required progress reports, do not apply while operating under such extensions. If the Permittee is required to submit progress reports as a condition of receiving an extension of compliance under 40 CFR 63.6(i), the Permittee shall submit such reports to the Control Officer by the dates specified in the written extension of compliance.

[40 CFR 63.366(a), 40 CFR 63.10(a), 40 CFR 63.10(d)]

a. The reports in Condition 56 shall include the following as applicable:

i. Performance Test Reports

(a) The Permittee shall report the results of a required PT to the Control Officer. The Permittee shall report the results of the PT to the Control Officer before the close of business on the 60th day following the completion of the PT, or as approved otherwise in writing by the Control Officer. The results of the PT shall be submitted as part of the notification of compliance status required under Condition 57.f.v and shall list:

- (i) The methods that were used to determine compliance;
- (ii) The results of any PT's, when requested by the Control Officer, continuous monitoring system (CMS) performance evaluations, and/or other monitoring procedures or methods that were conducted;
- (iii) The methods that will be used for determining continuing compliance, including a description of monitoring and reporting requirements and test methods;
- (iv) The type and quantity of hazardous air pollutants emitted by the source (or surrogate pollutants if specified in the relevant standard), reported in units and averaging times and in accordance with the test methods specified in the relevant standard;
- (v) A description of the air pollution control equipment (or method) for each emission point, including each control device (or method) for each hazardous air pollutant and the control efficiency (percent) for each control device (or method); and
- (vi) A statement by the Permittee as to whether the source has complied with the standards and requirements in Condition 45.

ii. CMS Performance Evaluation (if requested)

The Permittee shall furnish a written report of the results of the CMS performance evaluation, as required by 40 CFR 63.8(e), simultaneously with the results of the PT, when requested by the Control Officer in accordance with Condition 52.d.v.

[40 CFR 63.10(e)(2)(i)]

iii. Excess Emissions and (CMS) Performance and Summary Reports.

[40 CFR 63.10(e)(3)]

- (a) Pursuant to 40 CFR Part 63.10(e)(3)(iii) and 63.10(f), the Permittee shall submit an excess emissions and continuous monitoring system (CMS) performance report and/or a summary report to the Control Officer annually, except when
 - (i) The Control Officer requests that more frequent reporting is necessary to accurately assess the compliance status of the source; or

- (ii) The affected source is complying with the Performance Track Provisions of 40 CFR § 63.16, which may allow less frequent reporting.
 - (b) **Request to reduce reporting frequency:** Notwithstanding the frequency of reporting Condition 57.a.iii, if the Permittee is required to submit excess emissions and continuous monitoring system performance (and summary) reports on a semiannual (or more frequent) basis, the Permittee may reduce the frequency of reporting if the following conditions are met:
 - (i) For 1 full year (e.g., 4 quarterly or 12 monthly reporting periods) the affected source's excess emissions and continuous monitoring system performance reports continually demonstrate that the source is in compliance with the relevant standard;
 - (ii) The owner or operator continues to comply with all recordkeeping and monitoring requirements; and
 - (iii) The Control Officer does not object to a reduced frequency of reporting for the affected source, as provided below.
 - (c) The Permittee may request approval by the administrator of the EPA to reduce the frequency of excess emissions and continuous monitoring system performance (and summary) reports in accordance with provisions in 40 CFR 63.10(e)(3)(iii) or 40 CFR § 63.16.
 - (d) As soon as CMS data indicate that the source is not in compliance with any emission limitation or operating parameter, the frequency of reporting shall revert to the frequency specified by the Control Officer and as stated in 40 CFR Part 63.366(a)(3), and the Permittee shall follow the procedures in Conditions 57.a.iii.(b) and demonstrate ongoing compliance for another full year to again request to reduce the reporting frequency.
- iv. **Summary report to be submitted as provided in Conditions 56.b.ii and 57.a.iii.**

As required under Condition 57.a.v and vi below, a summary report shall be submitted for the HAP monitored. The summary report shall be entitled “Summary Report—Gaseous and Opacity Excess Emission and Continuous Monitoring System (CMS) Performance” and shall contain the following information:

- (a) The company name and address of the affected source;
- (b) An identification of each hazardous air pollutant monitored at the affected source;
- (c) The beginning and ending dates of the reporting period;
- (d) A brief description of the process units;
- (e) The emission and operating parameter limitations specified in the relevant standard(s);
- (f) The monitoring equipment manufacturer(s) and model number(s);
- (g) The date of the latest CMS certification or audit;
- (h) The total operating time of the affected source during the reporting period;
- (i) An emission data summary (or similar summary if the owner or operator monitors control system parameters), including the total duration of excess emissions during the reporting period (recorded in minutes for opacity and hours for gases), the total duration of excess emissions expressed as a percent of the total source operating time during that 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 equipment problems, process problems, other known causes, and other unknown causes;

- (j) A CMS performance summary (or similar summary if the owner or operator monitors control system parameters), including the total CMS downtime during the reporting period (recorded in minutes for opacity and hours for gases), the total duration of CMS downtime expressed as a percent of the total source operating time during that reporting period, and a breakdown of the total CMS 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;
 - (k) A description of any changes in CMS, processes, or controls since the last reporting period;
 - (l) The name, title, and signature of the responsible official who is certifying the accuracy of the report; and
 - (m) The date of the report.
- v. **Summary Report if Exceedances are < 1%, and CMS downtime > 5%** [40 CFR 63.10(e)(3)(vii)]

If the total duration of excess emissions or process or control system parameter exceedances for the reporting period is less than 1 percent of the total operating time for the reporting period, and CMS downtime for the reporting period is less than 5 percent of the total operating time for the reporting period, only the summary report shall be submitted, and the full excess emissions and continuous monitoring system performance report in Condition 57.a.iii need not be submitted unless required by the Administrator.

- vi. **Excess Emission & Summary Report if Exceedances > 1% and CMS downtime > 5%**

If the total duration of excess emissions or process or control system parameter exceedances for the reporting period is 1 percent or greater of the total operating time for the reporting period, or the total CMS downtime for the reporting period is 5 percent or greater of the total operating time for the reporting period, both the summary report and the excess emissions and continuous monitoring system performance report in Condition 57.a.iii shall be submitted and include the additional information in 52.e.i.(b)(ii) through (viii).

[40 CFR 63.10(e)(3)(vii)]

- b. **Reports required by 40 CFR 63.10 may be sent by U.S. mail, fax, or by another courier.**
- i. Submittals sent by U.S. mail shall be postmarked on or before the specified date.
 - ii. Submittals sent by other methods shall be received by the Control Officer and Administrator on or before the specified date.
- c. If acceptable to both the Control Officer and the Permittee, reports may be submitted on electronic media.
- d. **Content and submittal dates for deviations and monitoring system performance reports.**

All deviations and monitoring system performance reports and all summary reports, if required per Conditions 57.a.iii and 57.a.iv, shall be delivered or postmarked within 30 days following the end of each semiannual or annual period as provided in Condition 56.a. Written reports of deviations from an operating limit shall include all information required in Conditions 52.e.i.(b)(ii) through (viii) and information from any calibration tests in which the monitoring equipment is not in compliance with PS 9 or the method used for temperature calibration. The written report shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report.

e. **Application to Construct or Reconstruct**

The Permittee shall submit an application to revise this permit and/or to construct a new source or reconstruct an existing source pursuant to 40 CFR 40 CFR 63.366(b) and Condition 14.a.iii as follows:

- i. Requirement for Application [40 CFR 63.366(b)(3)(i)(B)]
 - (a) The Permittee may use the application for approval of construction or reconstruction to fulfill the initial notification requirements Condition 57.f i. [40 CFR § 63.366(c)(1)(B)]
 - (i) For a new or reconstructed source subject to 40 CFR 63, Subpart O for which an application for approval of construction or reconstruction is required under 40 CFR 63.366(b)(3)(ii), The Permittee shall provide the following information in writing to the Control Officer:
 - (ii) A notification of intention to construct a new source subject to these emissions standards, reconstruct a source subject to these emissions standards, or reconstruct a source such that the source becomes a source subject to these emissions standards with the application for approval of construction or reconstruction as specified in 40 CFR 63.366(b)(3)(i)(A);
 - (iii) A notification of the date when construction or reconstruction was commenced, delivered or postmarked no later than 30 days after such date.
 - (iv) A notification of the anticipated date of startup of the source, delivered or postmarked not more than 60 days nor less than 30 days before such date; and
 - (v) A notification of the actual date of initial startup of the source, delivered or postmarked within 15 calendar days after that date.
 - (b) A separate application shall be submitted by the Permittee for each construction or reconstruction and shall include at a minimum:
 - (i) The applicant's name and address.
 - (ii) A notification of intention to construct a new source subject to 40 CFR 63, Subpart O or make any physical or operational change that may meet or has been determined to meet the criteria for a reconstruction.
 - (iii) The address (i.e., physical location) or proposed address of the source.
 - (iv) An identification of the relevant standard that is the basis of the application.
 - (v) The expected commencement date of the construction or reconstruction.
 - (vi) The expected completion date of the construction or reconstruction.
 - (vii) The anticipated date of (initial) startup of the source.
 - (viii) The type and quantity of hazardous air pollutants emitted by the source, reported in units and averaging times and in accordance with the test methods specified in the standard, or if actual emissions data are not yet available, an estimate of the type and quantity of hazardous air pollutants expected to be emitted by the source reported in units and averaging times specified. The owner or operator may submit percent reduction information, if the standard is established in terms of percent reduction. However, operating parameters, such as flow rate, shall be included in the submission to the extent that they demonstrate performance and compliance.
 - (ix) Other information as specified in 40 CFR 63.366(b)(3)(ii).

- (c) The Permittee shall submit the actual emissions data and other correct information as soon as available but no later than with the initial notification of compliance status report in Condition 57.f.v. [40 CFR 63.366(e)(2)]
- ii. The Control Officer may approve an application for construction or reconstruction if the Permittee demonstrates to the Control Officer's satisfaction that the conditions in 40 CFR 63.366(b)(4) have been met. [40 CFR 63.366(b)(4)]
- iii. The Permittee shall notify the Control Officer of the intended construction or reconstruction of an affected source. The notification in Condition 57.f.i shall be submitted in as soon as practicable before the construction or reconstruction is planned to commence. The notification shall be submitted as soon as practicable before the initial startup date, but no later than 60 days after the effective date, if the construction or reconstruction had commenced and the initial startup date has not occurred before the effective date in 40 CFR 63 Subpart O.
- iv. The owner or operator of an affected source with an initial startup before the effective date of a relevant standard under 40 CFR Part 63 shall notify the Control Officer in writing that the source is subject to the relevant standard. The notification, which shall be submitted not later than 120 calendar days after the effective date of the relevant standard (or within 120 calendar days after the source becomes subject to the relevant standard), shall provide the following information: [40 CFR 63.9(b)(2)]
 - (a) The name and address of the owner or operator;
 - (b) The address (i.e., physical location) of the affected source;
 - (c) An identification of the relevant standard, or other requirement, that is the basis of the notification and the source's compliance date;
 - (d) A brief description of the nature, size, design, and method of operation of the source and an identification of the types of emission points within the affected source subject to the relevant standard and types of hazardous air pollutants emitted; and
 - (e) A statement of whether the affected source is a major source or an area source .
- v. The owner or operator of any existing sterilization facility shall also include the amount of ethylene oxide used during the previous consecutive 12-month period in the initial notification report required by 40 CFR 63.9(b)(2) and (3). For new sterilization facilities subject to this subpart, the amount of ethylene oxide used shall be an estimate of expected use during the first consecutive 12-month period of operation.

f. **Notification Requirements**

The Permittee shall fulfill all notification requirements in 40 CFR 63.9 according to the applicability in Table 1 of 40 CFR 63.360 and Condition 9 unless otherwise agreed to by approval of the Control Officer and/or Administrator of the US EPA. Applicable notifications may include the following:

- i Initial Notification and Approval of Construction. Note; (See – 40 CFR 69.9(b))
- ii Requests for Extension of Compliance; (See – 40 CFR 63.9(c))
- iii Performance Test Notifications – (See – 40 CFR 63.9(e))
- iv Additional Reporting Requirements for Sources with CMS systems – (See 40 CFR 63.9(g))
- v Notification of Compliance Status – (See 40 CFR 63.9(h))
- vi Adjustments to Time Periods or Postmark Deadlines (See 40 CFR 63.9(i))
- vii Notifications of Changes to Information Already or Previously Provided (See 40 CFR 63.9(j))
- viii Electronically submitted Notifications (See 40 CFR 63.9(k))

ATTACHMENT 5: SUMMARY OF MONITORING, RECORDKEEPING AND REPORTING

Green colored row identifies reporting & notification requirements

Blue denotes ancillary equipment requirements per GP 6205

Section. Condition	Description
§§ 1 - 3: General Provisions	
§ 1.7	Permit Posting & Equipment Identification
§ 1.9;	General Reporting and Notifications
§ 1.11	Excess Emissions and Emergency Reporting
§ 1.12.a, b & c	General Recordkeeping & Correspondence
§ 1.14	Amendment, Revision, Facility Change
§ 1.19	Other Required Activity Permits
§ 1.15.e & 1.15.h	Testing Notifications and Reports (when applicable)
Permit-Wide	
§ 4.42	Source O & M plans and records
§ 4.46	Facility EO Emission Limit and Cap
§ 5.51.a	Records of 12-month averages or rolling totals of the following: -Facility EO Emissions – limited to 709 lb as 12-month rolling total -APC hourly emissions data; Average catalyst temperature -EO Usage -Average pressure drop for APC's 3 - 8; -Average Building Management system parameters
§ 5.51.b ; § 5.51.c;	If required by <u>Attachment 6</u> or request of Control Officer the following records: - Visible emission (VE) checks, VE investigations, VE determinations & corrective actions - Necessary and feasible precautions taken to prevent fugitive dust emissions
§ 5.51.d;	Copies of any required activity permits obtained during term of permit (open burn, fugitive dust, and asbestos demolition-renovation).
§ 5.51.f;	Records of correspondence from Control Officer requesting any additional monitoring.
§ 5.51.g	Reference to summaries of monitoring and recordkeeping for permit and O & M plan attachments
§ 5.56a	Periodic Reporting Annual Summary Report of Required monitoring to include: - 12-month rolling total EO usage of facility - Facility EO Cap Spreadsheet - For APC 1 & 2 monitored discharge rates results and summary of required monitoring and emission discharge rates and associated CEMS data collection summary - For APC 3 – 8 monitored discharge rates results and summary of required monitoring and emission discharge rates and associated CEMS data collection summary - Summary and duration of deviations and malfunctions, down-times, and corrective actions - Annual log of facility changes Annual NESHAP Subpart O Report
§ 5.56.b	Special Reporting and Notifications - Submission of O & M Plan for APC 3 – 8 for approval before startup - CEMS monitoring Plan - NESHAO Subpart O notifications and reports
§ 5.57.a.iv	Annual NESHAP Subpart O Excess Emission & CMS performance Reports
§ 5.58	Monthly Report for Public Access

Section. Condition	Description
Fugitive EO Emissions Control	
§ 5.53.a	Operate dedicated CEMS on startup and install required monitoring devices; operate in accordance with Condition 55; Using hourly data reduce and summarize emissions for each operating hour, day, and month. Use operating month APC emissions to determine compliance with facility cap; Invalid or missing data provisions for entry's in facility cap spreadsheet.
§ 5.53.b	Keep the following records: <ul style="list-style-type: none"> - Monitor and record the EO usage each month - Hourly emission rate data, in addition summary of average EO emitted each operating day and month from each APC and the calculated monthly facility emissions recorded in the "Facility Cap Spreadsheet" - Approved O & M Plan records for APC 3-8 and building mgmt. parametric monitoring: - Daily, monthly, and quarterly inspection forms (as applicable) and reports for APC 3-8 - Applicable building management system parameters to include determination of capture efficiency for Areas 1, 2, and 3, and average times or duration doors were open and negative pressure indicators were positive. - Maintenance Logs for each APC and fan, ducting control system. - Log of deviations from parameters or malfunctions and their duration - Hours of operation and times removed from service for maintenance or other reasons - Periodic visual inspections of dry bed media, emission rate tracking, APC performance graphs and remaining media capacity
NESHAP Subpart O Requirements	
§ 5.52	Conduct initial performance test. Note RATA test may be used in lieu of performance test; Per management practices and chosen CMS option, continuously monitor catalyst operating temperature every 15 minutes; and Maintain CMS (Oxidation Temp) monitoring instruments per CMS O & M Plan.
§ 5.52.e	Recordkeeping Requirements
§ 5 – GP #6205 – Fossil Fuel Fired Equipment (GP 6205 – Fuel Burning Equipment)	
GP #6205 – § 5.51.a	Demonstrate that Natural Gas is the only fuel plumbed to the boilers for firing
GP 6205 – § 5.52.e	Not required to conduct visible emission checks;
§ 6C – GP # 6205 – NSPS for CI ICE (GP 6205 – Fuel Burning Equipment)	
GP #6205 – § 6C.65.a	Operating hours: Monthly records of operating hours and 12-consecutive month totals; As applicable, emergency and non-emergency hours of operation;
GP #6205 – § 6C.65.b	Compliance Records for: <ul style="list-style-type: none"> - Pre-2007 model year CI ICE; - 2007 model year and later CI ICE - Non-Certified CI ICE
GP #6205 – § 6C.65.c	Records of Monthly Visible emission check on exhaust stack of each engine if run during the month.
GP #6205 – § 6C.65.d	Records that verify compliance with the diesel fuel requirements.
GP #6205 – § 6C.65.e	Annual Report (if applicable): requirement to submit report to EPA for emergency CI ICE that operate for non-emergency peak shaving, demand response, or to generate income to supply power.

ATTACHMENT 6: ADDITIONAL ANCILARY EQUIPMENT REQUIREMENTS

1. GP 6205 – Fuel Burning Equipment

- a. The following Sections of GP #6205 apply to the facility and any ancillary sources listed in the equipment list:

- § 3 – Permit Applicability

- § 4 – Permit-Wide Operations

- § 5 – Fossil Fuel Fired Industrial and Commercial Equipment (Boilers and Heaters)

- § 6C – NSPS Requirements for ‘CI’ ICE

- § 8 – Specific Source Applicability

- b. Specific Applicability for Item 5 of the equipment list:

- Condition 80: Permitted Facility Sources

- Condition 80.a: Permit-Wide Operations

- Condition 80.b: Fossil-Fuel Fired Industrial and Commercial Equipment (Boilers & Heaters)

- Condition 80.e.iii: New Source Performance Standards for CI ICE

- Condition 81: Local (New and Existing) Stationary Source Performance Standards.

- Condition 82: Exempt Sources.

ATTACHMENT 7: APPROVED O & M Plans for APC and CMS systems

Plans to be submitted prior to startup per Conditions [42.c](#), [46.b.i](#) and Condition [52.d.iii\(a\)\(ii\)](#).