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: EXPIRES:

Rupesh Patel, Air Program Manager, PDEQ
SIGNATURE TITLE
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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. BD operates over 20 sterilization sites globally, 12 of which are ethylene oxide sterilization facilities. This permit authorizes the construction and operation of their proposed new ethylene oxide sterilization facility for the purpose of sterilizing various medical products to include 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 which constitute the facility or installation fall under the following industrial classification:


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 National Emission Standards for Hazardous Air Pollutants (NESHAP) Subpart O in 40 CFR Part 63. The source is a Minor Source of conventional pollutants and an Area Source of HAPs.

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 has been designed around a use of approximately 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. These systems are designed with 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 to be highly efficient at reducing EO process gas emissions and has been used in the global medical sterilization industry for many years and designed to exceed current EPA NESHAP Subpart O standards for the industry.

Per the NESHAP Subpart O standard, the LESNI® cat-ox abatement system(s) Air Pollution Control – (APC 1 & 2) are limited to not exceed 1 PPMV at the discharge vent(s). The LESNI systems will be equipped with a continuous temperature monitoring system and will be performance tested annually to measure and verify their emission rate.
The fugitive emissions will be effectively collected and controlled from (6) distinct work areas with Advanced Air Technology® dry bed system(s) using dry bed scrubbers designed with a specialized dry media (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).
- **Area 2** – Sterilization Chamber Areas (includes the sterilization chamber rooms, and damage limiting construction (DLC) areas).
- **Areas 3 – 6** Work In Progress (WIP) & Post-Sterile Warehouse Areas. The area will be equipped with 4 independent APC Units (APC 5 – 8).

Emissions from Area 1 (APC 3) will be controlled using dry bed system(s). The emissions discharged from this APC are limited not to exceed 100 micrograms per cubic meter.

Emissions from Area 2 (APC 4) will be controlled using dry bed system(s). The emissions discharged from this APC are limited not to exceed 100 micrograms per cubic meter.

Emissions from Areas 3 – 6 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.

**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 on a 12 month rolling basis to be demonstrated by periodic performance test (PT) monitoring of the EO discharge rates at each of the stack/vent discharge points and tracking compliance on a quarterly basis.

**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 such revision, pay the applicable fee pursuant to Condition 8. (See Condition 14 for the general requirements regarding facility changes and if a permit revision is required).

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 criteria pollutants, the area source threshold for hazardous air pollutants (HAPs), and/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 additional specific attachments for 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 provided in the permit and in the permit 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).

<table>
<thead>
<tr>
<th>Source Type and Category</th>
<th>Conventional or Criteria Air Pollutants</th>
<th>NSPS or NESHAP Pollutants</th>
<th>HAP(s)</th>
<th>CO₂e</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PM₁₀</td>
<td>PM₂·₅</td>
<td>PM</td>
<td>NOₓ</td>
</tr>
<tr>
<td>Sterilization ¹</td>
<td>-</td>
<td>-</td>
<td>0.36</td>
<td>-</td>
</tr>
<tr>
<td>Boilers</td>
<td>0.82</td>
<td>0.82</td>
<td>0.82</td>
<td>1.17</td>
</tr>
<tr>
<td>Fire Pump</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.01</td>
</tr>
<tr>
<td>Generator</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.03</td>
</tr>
<tr>
<td>Total Estimated Emissions</td>
<td>0.82</td>
<td>0.82</td>
<td>0.82</td>
<td>1.21</td>
</tr>
</tbody>
</table>

¹ These are the estimated of point source emissions from the LESNI and Advanced Air Technology dry bed air pollution control devices (APC). See the TSD for detailed discussion of the emission estimates and emission points and permit-wide 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 terms and Conditions in this permit change, 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 NEHSHAP 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: NESHAP 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

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

40. Permit-Wide Limits

41. General Control Requirements

42. Operation and Maintenance Requirements
43. Opacity

[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 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 44 and 45.b, Conditions 44 and 45.b shall not apply. [PCC 17.16.040.B]

44. Visibility

[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 Air Quality Control. 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]

46. Fugitive EO Emission Control [PCC 17.11.190.B, PCC 17.13.070]

The fugitive EO emission control provisions below apply 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 (Attachment 2 of this permit).

a. Facility-Wide EO Emission Cap [PCC 17.11.190.B & PCC 17.13.070] [Federally Enforceable Conditions]

The Permittee shall not exceed the following EO emission limit as determined from PT results using the monitoring and testing procedures in Condition 53.a and 55:

i. 709 lb of EO monitored as a 12-month rolling total.

b. The Permittee shall install, operate, and maintain the Advanced Air Technologies® APC in Table 2 and the equipment list (Attachment 2 of this permit) to effectively control fugitive EO emissions to levels less than the limits in Table 2 and shall operate the APC at all times while the facility is in operation, except for periods of malfunction in accordance with the following: [PCC 17.11.190.B]

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. The Permittee may propose or request a revision or modification to the O&M plan without a reopening of this permit two years after startup in accordance with Conditions 53.a.ii.(b) and 14.c. The O & M plan shall address and establish records and procedures to verify at a minimum the following items: [PCC 17.12.040.A.2]

(a) Description of the O & M plan to be followed to verify proper operation and integrity of the APC to include but not limited to the following:

(i) Daily pressure differential measured across the dry bed systems;

(ii) Periodic visual inspection of the dry bed media;

(iii) Proposed PT testing strategy and schedule per Condition 53.a.ii; and

(iv) Maintenance of the fan, ducting, and control systems.

(b) Tracking of the PT results from the scheduled testing in Table 2 below and determining the emission rates for compliance with the monitoring in Condition 53 and documenting each APC’s performance and remaining media capacity in units of remaining tons of EO use and estimated time until change-out.
(c) For each APC, the procedures, periodic inspection forms, and records to document the following:

(i) Daily pressure differential (or pressure drop) and verification of building management system parameters;

(ii) Amount of EO used since the 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;

(v) Any corrective actions taken to restore units or parameters to their proper function.

(vi) Deviations, or malfunctions and their duration;

(d) In the O&M Plan, the Permittee shall identify periodic measurements and parameters to be collected and monitored by the building management system verifying proper collection of fugitive EO emissions from areas downstream of any natural draft openings and outer areas. Compliance shall be monitored and demonstrated to meet the following criteria:

(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 will be monitored by the building management system.

(iii) The areas shall be kept 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.
## Condition 46, Table 2 – APC Emission & Operating Limits, and Testing Schedule

<table>
<thead>
<tr>
<th>Description</th>
<th>Emission and Operating Requirements</th>
<th>Test Schedule ¹, Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Source ID 07 – Area 1, APC – 3 Gas Room Areas;</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• The gas dispense (day tank) room(s);</td>
<td>EO Limits: 100 µg/m³; Compliance with the limits shall be tested and monitored each calendar quarter per Condition 53.a.ii.</td>
<td>Each calendar quarter following startup</td>
</tr>
<tr>
<td>• Vaporizer room(s);</td>
<td></td>
<td></td>
</tr>
<tr>
<td>**Source ID 08 – Area 2, APC – 4 Sterilization Areas;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Damage Limiting Construction</td>
<td>EO Limits: 100 µg/m³; Compliance with the limits shall be tested and monitored each calendar quarter per Condition 53.a.ii.</td>
<td>Each calendar quarter following startup</td>
</tr>
<tr>
<td>• Sterilization Chamber and Aeration Room(s)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Source ID 09 – Area 3, APC – 5 Post-Sterilization Area,</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Work-In-Progress Warehouse (WIP)</td>
<td>EO Limits: 200 µg/m³; Compliance with the limits shall be tested and monitored each calendar quarter per Condition 53.a.ii.</td>
<td>Each calendar quarter following startup</td>
</tr>
<tr>
<td>• Post Sterile Area</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Source ID 10, Area 4, APC – 6 Post Sterilization Area,</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Work-In-Progress Warehouse (WIP)</td>
<td>EO Limits: 200 µg/m³; Compliance with the limits shall be tested and monitored each calendar quarter per Condition 53.a.ii.</td>
<td>Each calendar quarter following startup</td>
</tr>
<tr>
<td>• Post-Sterile Area</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Source ID 11, Area 5, APC – 7 Post Sterilization Area,</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Work-In-Progress Warehouse (WIP)</td>
<td>EO Limits: 200 µg/m³; Compliance with the limits shall be tested and monitored each calendar quarter per Condition 53.a.ii.</td>
<td>Each calendar quarter following startup</td>
</tr>
<tr>
<td>• Post Sterile Area</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Source ID 12, Area 6, APC – 8 Post Sterilization Area,</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Work-In-Progress Warehouse (WIP)</td>
<td>EO Limits: 200 µg/m³; Compliance with the limits shall be tested and monitored each calendar quarter per Condition 53.a.ii.</td>
<td>Each calendar quarter following startup</td>
</tr>
<tr>
<td>• Post Sterile Area</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

APC – Air Pollution Control System;

¹ Test schedule subject to modification per O & M Plan pursuant to Condition 53.a.ii.(b).

² Compliance with the flow parameters and performance shall be periodically monitored in accordance with the approved O & M plan in Condition 46.c.

### 47. Ancillary Operations (See Attachment 6) (Boilers & Generators)

a. 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

§ 5a: Monitoring and Recordkeeping

50. General Recordkeeping

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

51. Permit-Wide

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 quarterly 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 in accordance with Condition as an excess emission in accordance with Condition 11.

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 4 for a summary of the monitoring, recordkeeping, and reporting required by this permit. See Attachment 5 of the TSD for any O&M plans, sample forms or checklists that may be used to comply with the Conditions in this permit.
52. NESHAP Subpart O (See Attachment 4)  
[Federally Enforceable Conditions]

53. Fugitive EO Emission Controls  
[PCC 17.13.020.A.3 & 4, PCC 17.11.190B & PCC 17.13.070]

a. Facility-Wide EO Emissions Cap Monitoring
   i. APC units 1 and 2 – Process EO Emissions
      (a) The emission rates of APC units 1 and 2 shall be calculated from the results of the most recent PT. Following the initial test in Condition 52.a., subsequent PT’s shall be conducted within 12 months. The emission rates, in lb/month, shall be determined and recorded in the EO Cap Spreadsheet in Condition 53.b.ii to determine compliance with the limit in Conditions 46.a.i.
      (b) Should APC units 1 and 2 fail the initial performance test, the Permittee shall investigate and attempt to tune or correct the system controls and conduct a re-test within 90 days following the failed PT, until such time that the system(s) can demonstrate compliance. Notwithstanding a failure to meet the standard in Condition 45.b.i the Permittee shall be required to enter the determined emission rate for each month until the unit is retested in the Emission Cap Spreadsheet in Condition 53.b.ii to determine compliance with Condition 46.a.i until a retest or investigation would otherwise change such a finding.
   ii. APC units 3 – 8 Fugitive EO Emissions
      (a) Within 180 days of initial startup, the Permittee shall:
         (i) Conduct periodic PT’s of the APC according to the test schedule listed in Table 2 of Condition 46 and methods and procedures in Condition 55 to verify the compliance with the limits in Table 2 of Condition 46. The measured rates shall not exceed the limits in Table 2 of Condition 46. In the event the PT exceeds the limits, the Permittee shall correct the condition as soon as possible but no longer than 60 days from receiving the test results.
         (ii) Following each PT, the EO discharge rates in lb/month, shall be recorded in the EO Emission Cap spreadsheet following the procedure in Condition 53.b.ii. The 12-month rolling totals shall not exceed the emission cap in Conditions 46.a.i.
         (iii) Within the first two years following initial startup, the Permittee shall conduct PT’s and monitor compliance within 14 days of the frequency scheduled in Table 2 of Condition 46. Thereafter the Permittee must follow the schedule as provided in an approved O & M Plan pursuant to Condition 53.a.ii(b) below.
         (iv) The air flow during the PT’s shall be measured from the APC discharge vents and shall be monitored and verified to be within 5% of the rated air flow design parameters in the equipment list in accordance with the procedures in Condition 55.c.
      (b) Revisions to the O & M plan
         (i) Following the first 2 years after startup defined in Condition 52.a, and a determination by the Control Officer that the Advanced Air Technology APC has demonstrated consistent and reliable performance upon review of the annual reports required by Condition 56.a.i(c), the Permittee may submit a request to revise the O & M plan in Condition 46.b.i to reduce the testing frequency. The plan revision shall discuss or propose reduced testing frequency in after considering the information in Condition 46.c.i.(b).
(ii) Following approval of a revised O & M plan allowing a reduced sampling schedule, if the Permittee monitors an exceedance of any of the limits in Condition 53.a.ii, or should the APC(s) performance reports required in Condition 56.a.ii(c) demonstrate inconsistent or unreliable performance, the Control Officer may require the Permittee to return to the increased PT sampling schedule in Table 2 for a period of time to demonstrate consistent and reliable performance before resuming the approved reduced PT schedule.

(iii) Each day the calculated emission rate exceeds the cap in Condition 46.a.i shall be considered an exceedance in accordance with Condition 11.a.

b. 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 calendar quarter and calculate a 12-month rolling total. [Federally Enforceable Condition]

ii. EO Cap Spreadsheet

The emission rate entries for each APC (1 – 8) shall be recorded monthly in a spreadsheet. Following initial startup, the emission rates for each APC for the previous operating months will be entered upon receipt of the PT results each calendar quarter. The 12-month rolling total shall be calculated each month for compliance with the emissions cap in Conditions 46.a.i. For purposes of calculating initial compliance with the 12-month rolling total on month 1 – initial startup, the 11 preceding months before the first PT results shall be assumed to be zero to represent non-operation of the facility. In addition, for purposes of missing data, should any PT be deemed to be invalid by the Control Officer, or a monthly period missed for any other purpose or reason, the highest previous entry since change-out of the dry bed media shall be entered for that month until a valid PT result is obtained.

iii. The approved O & M Plan with current testing schedule.

iv. A file with documentation for each APC to include the following:

(a) Daily, monthly, and quarterly inspection forms (as applicable), and 12-month average pressure differential and building management system parameters;

(b) Maintenance logs of for each APC, fan, ducting and control system;

(c) Log of deviations and malfunction from operating parameters, and their duration;

(d) Hours of operation and times removed from service for maintenance or other reasons; and

(e) Periodic visual inspections of the dry bed media, PT results and emission rate tracking, performance graphs, and remaining media capacity;
§5b: Testing

54. NESHAP Subpart O (See Attachment 4) [40 CFR 63.365] [Federally Enforceable Conditions]

55. Fugitive EO Emission Controls

a. The Permittee shall conduct scheduled PT in Table 2 of Condition 46 by collecting samples from the discharge streams of APC 3 – 8. For the purpose of these provisions, unless collecting duplicate samples, or conducting a series using a Reference Method to validate the Method, it shall only be required to conduct one sample run to measure the concentration. The discharge concentration shall be measured according to the test Methods in Condition 55.b, or other acceptable methods as approved by the Control Officer.

b. The Permittee shall use the following test methods and procedures, as applicable to measure the concentration of the discharge stream in APC 3 – 8 to verify they meet the limitations in Table 2 of Condition 46. To monitor overall performance of the dry bed systems, the performance will be tracked in accordance with Condition 46.c.i(b) relative to the emission rates, tons of EO used since media change-out, and estimated remaining life of the dry bed media. Test results will be reported in units of micrograms per cubic meter (ug/m³), and using the run hour information and days since the last PT, an emission rate in lb/month shall be determined. During the performance test the information on the APC, such as the operating parameters, and EO usage (media life) shall be documented:

i   Method TO 15A with GC/MS in Selective Ion Monitoring (SIM) acquisition mode

   (a) Samples will be collected and analyzed in Summa® canisters and analyzed using EPA Method TO-15A with GC/MS (Gas Chromatography/Mass Spectrometry) in the Selective Ion Monitoring (SIM) acquisition mode to determine the concentration of EO 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.

   ii Method TO 17 with GC/MS in Selective Ion Monitoring (SIM) acquisition mode.

   iii EPA Methods 18 and/or 25A, 320, Alt 141, and 142 using Fourier Transform Infra-red (FTIR).

c. To accommodate the selected sampling Method, sampling probes will be connected using flexible tubing (Teflon FEP, 1/4” OD), with the length not to exceed five (5) feet. Initially for the first set of quarterly PT’s, duplicate samples will be collected at the outlets from each dry bed system and submitted to the laboratory for determining the precision and repeatability of sample collection Methods and procedures. The samples will be collected according to the following procedure:

   i Sample duration: Sufficient time to obtain a representative sample, not less than 1 hour or as recommended by Method. (Three Runs may not be necessary)

   ii Sample Collection: Samples will be collected at a single point within each corresponding stack or duct of the dry bed system.
d. Air flow parameters: Outlet stack flow rate and moisture will be measured simultaneously by EPA Methods 1, 2, and 4 for each APC. The Permittee shall determine the velocity and volume of air flow through the discharge vents, and determine the moisture content. If found to be consistent during the first year of testing, the Permittee may request a waiver from the Control Officer to conduct Methods 1, 2, & 4 during subsequent PT’s once the average air flow rates have been firmly established relative to the APC’s differential pressure monitor. Thereafter, for purposes of calculating the EO emission rate, the highest volumetric rate previously recorded at a given APC differential pressure reading and average moisture level based on the relative humidity at the time of sampling may be used to estimate the emissions volume during a PT. Methods 1, 2, & 4 shall be used to verify the air flow parameters at least once each permit term to calibrate the air discharge volume from the vents relative to the measured differential pressure monitors of the APC.

e. The Permittee shall conduct a quarterly PT series, using the approved EPA Reference Method for NESHAP Subpart O sources, a year following startup, when the monitored APC concentrations are expected to be above the nominal EPA Methods 320, Alt 141, and 142 minimum detection levels. The Permittee shall also collect a set of duplicate samples at the time of testing in accordance with Condition 55.a and b to verify the consistency and accuracy of test methods and procedures chosen. Once the methods and procedures have been verified to provide test results within 10% of the Reference EPA method, the Permittee may use the most convenient method.

f. Initial PT’s shall require the submittal of a notification and test protocol in accordance with Condition 15.e. Once a protocol has been submitted and approved by the Control Officer, upon request and by mutual agreement with the Control Officer, the Permittee shall only be required to notify the Control Officer of scheduled PT’s without the submittal of test protocols.

g. Following the first 6 months after initial startup, and upon review and approval in accordance with Condition 15.h, if satisfied with the test procedures and methodology, and results of previous testing, 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 test date, the monitored APC, the measured EO concentration, and the determined emission rate. Also by mutual agreement, the summary reporting may be included in the annual summary report in Condition 56.a.i.c in lieu of being reported 30 days after each PT as required by Condition 15.h. Notwithstanding such 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 such reports upon request.
§ 5c: Reporting Requirements

56. Permit-Wide

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:

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 emissions rates showing compliance with the rolling 12-month rolling total in Condition 46.a.i. The spreadsheet shall be compiled quarterly.

(b) Performance test report and emission discharge rate(s) determined from the most recent PT of the LESNI cat-ox abatement system(s) APC 1 and 2.

(c) For APC 3 – 8, performance summary reports as required in Condition 46.c.i(b) to include the following:

(i) Summary of PT results, measured emission discharge rates, graphs with respect to time and EO usage, and projected remaining media capacity, compared to the expected or predicted performance based on the manufacturer's decay rate curves.

(ii) Summary and duration of deviations and malfunctions, APC unit(s) downtime or times taken out of service, and corrective actions necessary to restore APC or building management system parameters in accordance with the O & M plan.

(e) Annual log of facility changes in accordance with Condition 9.b.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 and/or notifications:

i. The O & M Plan in accordance with Condition 46.b.i.

ii. NESHAP Subpart O notifications and reports as applicable in accordance with Conditions 57.a.i, 57.a.ii, 57.e, and 57.f.

iii. Reports and notifications in Condition 9 as applicable.

57. NESHAP Subpart O (See Attachment 4)
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.


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.

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
17.13.240 Fees related to Class II and Class III permits.

Pima County Code Title 17, Chapter 17.14 – Activity Permits

Article I – General Provisions
17.14.080 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
17.16.430 Standards of performance for unclassified sources
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 46.a, 53.a]

2)  **Table 1 – EO Commercial Sterilization Line Process Emissions – (Phase 1 – ‘2023)**  
    [Ref. Conditions 40, 45, 52, 53, & 54]

<table>
<thead>
<tr>
<th>Source ID Number</th>
<th>Description</th>
<th>MFR</th>
<th>Model</th>
<th>Serial Number Unique ID</th>
<th>Maximum Rated Capacity</th>
<th>Operating Parameters &amp; Limitations</th>
<th>Fuels Used</th>
<th>Date of MFR</th>
<th>Date Installed</th>
</tr>
</thead>
</table>
| 01               | Sterilization Line 1; APC – 1, Cat-Ox Abatement System | LESNI | 10,000 | TBD | 225 tons EO/yr APC - 1&2 | Operating Parameter(s):  
Quarterly EO usage  
Average Catalyst Temp | Natural Gas | TBD | TBD |
| 02               | Sterilization Line 2; APC – 1, Cat-Ox Abatement System | Sterilization Chamber 1  
Aeration Room 1A  
Aeration Room 1B | LESNI | 10,000 | TBD | 225 tons EO/yr APC - 1&2 | Facility-wide Emissions Cap  
709lb as 12 month rolling total  
Recorded at least quarterly  
[Cond 40, 46.a, 53.b.i, 52.d] | Natural Gas | TBD | TBD |
| 03               | Sterilization Line 3; APC – 1, Cat-Ox Abatement System | Sterilization Chamber 3  
Aeration Room 3A  
Aeration Room 3B | LESNI | 10,000 | TBD | 225 tons EO/yr APC - 1&2 | NESHAP Subpart O STD,  
> 99% reduction efficiency or  
max.of 1 PPMv at the outlet  
Tested Annually  
[Cond 45.b.i, 53.a.(a), 52.b(c)(i)] | Natural Gas | TBD | TBD |

Proposed Monitoring Method: Periodic Performance (annual) Testing Using Method 18, 25A, and /or Alt 320 & 142 & Continuous Temperature Monitoring
Continuous Monitoring System² (CMS) – “LESNI Abatement system(s) – Oxidation temp monitored using digital acquisition and handling systems (DAHS)  
[See Conditions 52.a & c]

TBD – To be Determined
### Table 1 (continued) – EO Commercial Sterilization Line Process Emissions – (Phase 2 – ‘2025)

[Ref. Conditions 45, 52, 53, 54, & 56]

<table>
<thead>
<tr>
<th>Source ID Number</th>
<th>Description</th>
<th>MFR</th>
<th>Model</th>
<th>Serial Number Unique ID</th>
<th>Maximum Rated Capacity</th>
<th>Operating Parameters &amp; Limitations</th>
<th>Fuels Used</th>
<th>Date of MFR</th>
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</tr>
</thead>
</table>
| 04               | Sterilization Line 4; APC – 2, Cat-Ox Abatement System | LESNI | 10,000 | TBD ¹ | 225 tons EO/yr APC - 1&2 | Operating Parameter(s):  
  - Quarterly EO usage  
  - Average Catalyst Temp Facility-wide Emissions Cap  
    709lb as 12 month rolling total  
    Recorded at least quarterly  
    [Cond 40, 46.a, 53.b.i, 52.d]  
    NESHAP Subpart O STD,  
    > 99% reduction efficiency or max. of 1 PPM, at the outlet  
    Tested Annually  
    [Cond 45.b.i, 53.a.i(a), 52.bi(c)(i)]  
    APC CMS ²; Temp. DAHS  
    Recorded at least every 15 minutes  
    [Attachment 4, 52.e, 52.d] | Natural Gas | TBD | TBD |
| 05               | Sterilization Line 5; APC – 2, Cat-Ox Abatement System | LESNI | 10,000 | TBD | 225 tons EO/yr APC - 1&2 | Operating Parameter(s):  
  - Quarterly EO usage  
  - Average Catalyst Temp Facility-wide Emissions Cap  
    709lb as 12 month rolling total  
    Recorded at least quarterly  
    [Cond 40, 46.a, 53.b.i, 52.d]  
    NESHAP Subpart O STD,  
    > 99% reduction efficiency or max. of 1 PPM, at the outlet  
    Tested Annually  
    [Cond 45.b.i, 53.a.i(a), 52.bi(c)(i)]  
    APC CMS ²; Temp. DAHS  
    Recorded at least every 15 minutes  
    [Attachment 4, 52.e, 52.d] | Natural Gas | TBD | TBD |
| 06               | Sterilization Line 6; APC – 2, Cat-Ox Abatement System | LESNI | 10,000 | TBD | 225 tons EO/yr APC - 1&2 | Operating Parameter(s):  
  - Quarterly EO usage  
  - Average Catalyst Temp Facility-wide Emissions Cap  
    709lb as 12 month rolling total  
    Recorded at least quarterly  
    [Cond 40, 46.a, 53.b.i, 52.d]  
    NESHAP Subpart O STD,  
    > 99% reduction efficiency or max. of 1 PPM, at the outlet  
    Tested Annually  
    [Cond 45.b.i, 53.a.i(a), 52.bi(c)(i)]  
    APC CMS ²; Temp. DAHS  
    Recorded at least every 15 minutes  
    [Attachment 4, 52.e, 52.d] | Natural Gas | TBD | TBD |

Proposed NESHAP Subpart O – Monitoring Method: Annual Performance Testing Using Method 18, 25A, and /or Alt 320 & 142 & Continuous Temperature Monitoring Continuous Monitoring System ² (CMS) – “LESNI Abatement system(s) – Oxidation temp monitored using digital acquisition and handling systems (DAHS)”[See Conditions 52.a, 52.c]
4) **Table 2 – Fugitive EO Emission Control:**

<table>
<thead>
<tr>
<th>Source ID Number</th>
<th>Description</th>
<th>MFR</th>
<th>Model</th>
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<th>Maximum Rated Capacity</th>
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<th>Fuel Used</th>
<th>Date of MFR</th>
<th>Date Installed</th>
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<tr>
<td>07</td>
<td>APC-3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Operating Parameter(s):</td>
<td></td>
<td></td>
<td></td>
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</table>
| Volunteer Park   | EO Dry Bed  | Advanced Air Technologies | Safe Cell II DR490 (2 parallel beds, 2000 CFM each) | APC – 3 TBD | 4,000 CFM 3950 SCFM | - Quarterly EO usage  
- Pressure Drop  
- Bldg. Mgmt. Sys. Parameters per O & M Plan  
- Facility-wide Emissions Cap  
709lb as 12 month rolling total  
Recorded at least quarterly  
[Cond 40, 46.a]  
EO Discharge Limit:  
- 100 µg/m³  
[Cond 53.a.ii.(a)(i)] | N/A | TBD | TBD |
| 08               | APC-4       | Advanced Air Technologies | Safe Cell II DR490 (2 parallel beds, 2000 CFM each) | APC – 4 TBD | 24,000 CFM 23701 SCFM | Operating Parameter(s):  
Quarterly EO usage  
Pressure Drop  
Bldg. Mgmt. Sys. Parameters per O & M Plan  
Facility-wide Emissions Cap  
709lb as 12 month rolling total  
Recorded at least quarterly  
[Cond 40, 46.a]  
EO Discharge Limit:  
- 100 µg/m³  
[Cond 53.a.ii.(a)(i)] | N/A | TBD | TBD |
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<th>Fuel Used</th>
<th>Date of MFR</th>
<th>Date Installed</th>
</tr>
</thead>
</table>
| 09               | APC 5                               | Advanced Air Technologies | Safe Cell II DR490 10X-Parallel Systems | TBD                     | Fan: 20,000 CFM 19751 SCFM | Operating Parameter(s):  
Quarterly EO usage  
Pressure Drop  
Bldg. Mgmt. Sys. Parameters per O & M Plan  
Facility-wide Emissions Cap  
709lb as 12 month rolling total  
Recorded at least quarterly  
[Cond 40, 46.a]  
EO Discharge Limit:  
- 200 µg/m³  
[Cond 53.a.ii.(a)(i)] |
| 10               | APC – 6                             | Advanced Air Technologies | Safe Cell II DR490 10X-Parallel Systems | TBD                     | Fan: 20,000 CFM 19751 SCFM | Operating Parameter(s):  
Quarterly EO usage  
Pressure Drop  
Bldg. Mgmt. Sys. Parameters per O & M Plan  
Facility-wide Emissions Cap  
709lb as 12 month rolling total  
Recorded at least quarterly  
[Cond 40, 46.a]  
EO Discharge Limit:  
- 200 µg/m³  
[Cond 53.a.ii.(a)(i)] | N/A                                   | TBD                 | BD                                         |

Becton, Dickenson and Company (BD)  
Air Quality Permit # 6257  
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<table>
<thead>
<tr>
<th>Source ID Number</th>
<th>Description</th>
<th>MFR</th>
<th>Model</th>
<th>Serial Number/ Unique ID</th>
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<th>Fuel Used</th>
<th>Date of MFR</th>
<th>Date Installed</th>
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<tbody>
<tr>
<td>11</td>
<td>APC – 7 EO Dry Bed Scrubber</td>
<td>Advanced Air Technologies</td>
<td>Safe Cell II DR490 10X-Parallel Systems</td>
<td>TBD APC – 7</td>
<td>Fan: 20,000 CFM 19751 SCFM</td>
<td>Operating Parameter(s): Quarterly EO usage Pressure Drop Bldg. Mgmt. Sys. Parameters per O &amp; M Plan Facility-wide Emissions Cap 709lb as 12 month rolling total Recorded at least quarterly [Cond 40, 46.a] EO Discharge Limit: 200 µg/m³ [Cond 53.a.ii.(a)(i)]</td>
<td>N/A</td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>12</td>
<td>APC – 8 EO Dry Bed Scrubber</td>
<td>Advanced Air Technologies</td>
<td>DR490 Systems 10X-Parallel Systems</td>
<td>TBD APC – 8</td>
<td>Fan: 20,000 CFM 19751 SCFM</td>
<td>Operating Parameter(s): Quarterly EO usage Pressure Drop Bldg. Mgmt. Sys. Parameters per O &amp; M Plan Facility-wide Emissions Cap 709lb as 12 month rolling total Recorded at least quarterly [Cond 40, 46.a] EO Discharge Limit: 200 µg/m³ [Cond 53.a.ii.(a)(i)]</td>
<td>N/A</td>
<td>TBD</td>
<td>TBD</td>
</tr>
</tbody>
</table>
5) ATO under GP 6205 – Fuel Burning Equipment

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

Section 3 of the Permit – Boilers, Heaters, & Heaters:

<table>
<thead>
<tr>
<th>Source ID</th>
<th>Description/Location</th>
<th>MFR/Model</th>
<th>Serial Number/Unique ID</th>
<th>Maximum Rated Capacity</th>
<th>Date of MFR</th>
<th>Date Installed</th>
<th>Allowable Fuels and Annual Limits</th>
<th>Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Natural Gas (MMcf, hours, CF)</td>
<td>Fuel Oil (Gallons, hours, CF)</td>
</tr>
<tr>
<td>13</td>
<td>Boiler</td>
<td>TBD</td>
<td>TBD</td>
<td>8.17 MMBtu/hr</td>
<td>TBD</td>
<td>TBD</td>
<td>Unlimited</td>
<td>N/A</td>
</tr>
<tr>
<td>14</td>
<td>Boiler</td>
<td>TBD</td>
<td>TBD</td>
<td>8.17 MMBtu/hr</td>
<td>TBD</td>
<td>TBD</td>
<td>Unlimited</td>
<td>N/A</td>
</tr>
<tr>
<td>15</td>
<td>Boiler</td>
<td>TBD</td>
<td>TBD</td>
<td>8.17 MMBtu/hr</td>
<td>TBD</td>
<td>TBD</td>
<td>Unlimited</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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

Section 4C – NSPS for CI ICE (Emergency Designated Engines):

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

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.

Section 4C – Supplemental Requirements:

<table>
<thead>
<tr>
<th>Equip. No.</th>
<th>Applicable NSPS Emission Standard</th>
<th>NOx g/kw-hr (g/hp-hr)</th>
<th>NMHC g/kw-hr (g/hp-hr)</th>
<th>NMHC+NOx g/kw-hr (g/hp-hr)</th>
<th>CO g/kw-hr (g/hp-hr)</th>
<th>PM g/kw-hr (g/hp-hr)</th>
<th>Certified Emission Life (term, date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>Emergency Engine 2007 and later model year</td>
<td>--</td>
<td>--</td>
<td>6.4 (4.8)</td>
<td>3.5 (2.6)</td>
<td>0.20 (0.15)</td>
<td>8,000 hours or 10 years, whichever comes first</td>
</tr>
<tr>
<td>17</td>
<td>Fire Pump Engine 2009 and later model year</td>
<td>--</td>
<td>--</td>
<td>4.0 (3.0)</td>
<td>3.5 (2.6)</td>
<td>0.20 (0.15)</td>
<td>8,000 hours or 10 years, whichever comes first</td>
</tr>
</tbody>
</table>
ATTACHMENT 3: GENERAL CONDITIONS

§ 1: General Provisions


   a. The Permittee shall not commence construction of, operate, or make a modification to any source subject to regulation under Title 17 without first 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

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

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

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

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. 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

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

9. Reporting and Notifications

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.

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

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

(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

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

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
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
(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

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


   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

       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

       The Permittee shall promptly report 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.ai 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

       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**

   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**

      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**

      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**

   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**

   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

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).

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 other 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.

16. Property Rights

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

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.
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.


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. Wherever there is a disagreement of these terms with the rules referenced, the meaning in the rule shall prevail.

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]
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.
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 reinstalling 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 means the total equipment that may be required to meet the data acquisition and availability requirements of this part, used to sample, condition (if applicable), analyze, and provide a record of process or control system parameters.

Continuous emission monitoring system (CEMS) means the total equipment that may be required to meet the data acquisition and availability requirements of this part, used to sample, condition (if applicable), analyze, and provide a record of emissions.

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.

a. An emergency constitutes and 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:

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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 emission 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

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.

Initial startup date** means the date when a source subject to the emissions standards in §63.362 first begins operation of a sterilization process.

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.
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.

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 17.04.340.A.128.

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 physical or operational change does not include routine maintenance, repair or replacement.
- 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.
- 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:
   - Does not decrease the stringency of the compliance and enforcement measures for the relevant standard;
   - 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
   - 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:
   - Modifications to a sampling procedure, such as use of an improved sample conditioning system to reduce maintenance requirements;
   - Increased monitoring frequency; and
   - 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:
   - Does not decrease the stringency of the emission limitation or standard;
   - 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
   - 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:
   - 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
   - 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 standards contained in Chapter 17.16, 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;

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.

**Startup means** the setting in operation of an affected source or portion of an affected source for any purpose.

**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

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.

b. Standards

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.

i. Emissions from the sterilization chamber and aeration chamber vent shall be reduced by at least 99 percent or a maximum of 1 PPM, at the outlet of the LESNI® cat-ox abatement system(s) in the equipment list.

§ 5: Compliance Determination

§ 5a: Monitoring and Recordkeeping

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

a. Performance Testing

The Permittee shall complete the PT of each sterilization line 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

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.

(b) The operating limit shall consist of the recommended minimum oxidation temperature provided by the manufacturer for an operating limit.
(c) The Permittee shall comply with one of the following work practices:  

(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, 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:

(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  

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  

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

i. 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.

ii. 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 53.c.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) or 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.

(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
The temperature monitor being tested. As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards).

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.

(a) Operation and maintenance of continuous monitoring system (CMS).

(i) The Permittee must develop a written startup, shutdown, and malfunction plan for each CMS.

(ii) 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.

(iii) 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 readout (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.

(iv) 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.

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

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.

(a) The Permittee shall maintain relevant records for such source of:

(i) The occurrence and duration of each malfunction of operation (i.e., process equipment) or the required air pollution control and monitoring equipment;

(ii) Each period during which a CMS is malfunctioning or inoperative (including out-of-control periods);
(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); 

(iv) All results of PT’s, and when requested by the Control Officer, CMS performance evaluations;

(v) All measurements as may be necessary to determine the conditions of PT’s, and when requested by the Control Officer, performance evaluations;

(vi) All CMS calibration checks;

(vii) All adjustments and maintenance performed on CMS;

(viii) 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);

(ix) 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

54. NESHAP Subpart O

a. Performance Testing: The Permittee shall comply with the PT requirements in 40 CFR 63.7 in addition to the requirements herein.

b. Measuring Efficiency of the Sterilization Chamber Vent: California Air Resources Board (CARB) Method 431 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.

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:

   \[
   W_c = F_v \times t \times \%EO_v \times \left( \frac{MW}{SV} \right)
   \]

   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:

   \[
   \%EO_v = \frac{W_{EO}}{W_{EO} + \left( \frac{W_c}{MW} \right)}
   \]
where:

\[ W_{EO} = \text{weight percent of ethylene oxide} \]
\[ W_x = \text{weight percent of compound in the balance of the mixture} \]
\[ MW_x = \text{molecular weight of compound in the balance gas mixture} \]

(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:

\[ W_r = \frac{MW \times \%_{EO} \times P \times V}{R \times T} \]

where:

\[ W_r = \text{weight of ethylene oxide remaining in chamber (after the first evacuation), in g (lb)} \]

(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 Rootstype meters) 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 \((20 \, ^\circ C \text{ and } 101.325 \, kPa \text{ (68 } ^\circ F \text{ and 1 atm)})\) 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:

\[ W_o = C \times V \times \left( \frac{MW}{5V} \right) \times \frac{1}{10^6} \]

Where:

\[ W_o = \text{mass of ethylene oxide, g (lb)} \]
\[ C = \text{concentration of ethylene oxide in ppmv} \]
\[ V = \text{volume of gas exiting the control device corrected to standard conditions, L(ft}^3) \]
\[ 1/10^6 = \text{correction factor LEO/10}^6 \text{ LTOTAL GAS (ft}^3\text{EO/10}^6 \text{ ft}^3\text{TOTAL GAS)} \]

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

(e) Determine control device efficiency \( (% \text{Eff}) \) using the following equation:

\[ %\text{Eff} = \frac{W_f}{W_o} \times 100 \]

where:

\[ % \text{Eff} = \text{percent efficiency; } W_f = \text{mass flow rate into the control device} \]
\[ W_o = \text{mass flow rate out of the control device} \]
(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, the procedures outlined in Method 18 or Method 25A (40 CFR part 60, appendix A) shall be used. A Method 18 or Method 25A test consists of three 1-hour runs. If using Method 25A to determine concentration, calibrate and report Method 25A 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 using FTIR (Fourier Transform Infra-red) spectroscopy such as EPA Method 320 and ALT 142 have been approved by the Administrator of the EPA for measuring concentrations at lower detection levels and may be used to measure the EO concentration.

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 Method 18 or Method 25A in 40 CFR part 60, appendix A. A test is comprised of three 1-hour runs.

   ii. Determine control device efficiency (% Eff) using the following equation:

   \[
   \% \text{Eff} = \left( \frac{W_i - W_o}{W_i} \right) \times 100
   \]

   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

57. NESHAP Subpart O

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.

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.i 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.iv.

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

(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%**

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).

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. Construction and Reconstruction of New or Existing source

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 63.366(b) and Condition 14.a.iii as follows:

i. Requirement for Application

(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 not 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(c)(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

### Section, Condition | Description
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### §§ 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 |
| § 1.15.e & 1.15.h | Testing Notifications and Reports (when applicable) |

### Permit-Wide

| § 4.42 | Source O & M plans and records |
| § 5.51.a | Records of quarterly and 12-month averages or rolling totals of the following:  
- Facility Wide EO Emissions;  
- EO Usage;  
- Average catalyst temp for APC’s 1 & 2;  
- Average pressure drop for APC’s 3 through 8 |
| § 5.51.b ; § 5.51.c | If required by Attachment 6 or Control Officer the following records:  
- Visible emissions 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. |

### Periodic Reporting

| § 5.56a | Annual Summary Report of Required monitoring to include:  
- EO Emission Cap Spreadsheet  
- Most recent PT report and emission rate for APC 1-2  
- Performance summary reports for APC 3 – 8  
- Summary and duration of deviations and malfunctions, down-times, and corrective actions  
- Annual log of facility changes  
Annual NESHAP Subpart O Report |

### Special Reporting and Notifications

| § 5.56.b | - Submission of O & M Plan for APC 3 – 8 for approval before startup  
- NESHAP Subpart O notifications and reports |
| § 5.57.a.iv | Annual Continuous Monitoring System Report |
### Section. Condition | Description
--- | ---
### **Fugitive EO Emissions Control**

**§ 5.53.a** | Conduct Quarterly PT on APC 3 – 8 within 14 days of scheduled testing; verify airflow; and keep record of EO Emission Cap Spreadsheet to demonstrate compliance with EO emission cap.

**§ 5.53.b** | Keep the following records for APC 3 – 8 and Building Management Systems:
- Approved O & M Plan with testing schedule
- Daily, monthly, and quarterly inspection forms (as applicable) and reports.
- Maintenance Logs
- Log of deviations from parameters or malfunctions and duration
- Hours of operation and times removed from service for maintenance or other reasons
- Periodic visual inspections of dry bed media
- PT results and emission rate tracking, remaining media capacity

### NESHAP Subpart O Requirements

**§ 5.52** | Conduct initial and annual performance tests per management practices; and Continuously monitor catalyst operating temperature every 15 minutes; and Maintain CMS (Oxidation Temp) DAHS per CMS O & M Plan.

**§ 5.52.e** | Recordkeeping Requirements

### § 3 - Fossil Fuel Fired Equipment (Section References to GP 6205)

**§ 3.36.a** | Demonstrate that Natural Gas is the only fuel plumbed to the boilers for firing

**§ 3.38** | Not required to conduct visible emission checks;

### § 4C – NSPS for CI ICE (Section References are to GP 6205 – Fuel Burning Equipment)

**§ 4C.58 & 59**<br>**§ 4C.63** | Operating hours: Monthly records of operating hours and 12-consecutive month totals; As applicable, emergency and non-emergency hours of operation;

**§ 4C.60** | Compliance Records for:
- Pre-2007 model year CI ICE;
- 2007 model year and later CI ICE
- Non-Certified CI ICE

**§ 4C.61.d** | Records of Monthly Visible emission check on exhaust stack of each engine if run during the month.

**§ 4C.62** | Records that verify compliance with the diesel fuel requirements.

**§ 4C.64** | 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

ANCILARY EQUIPMENT
ADDITIONAL ATTACHMENTS
(as applicable)

GP 6205 – Fuel Burning Equipment

1) The following Sections of GP #6205 apply to the facility and any ancillary sources listed in the equipment list:
   Section 1 – General Applicability
   Section 2 – Permit-Wide Operations
   Section 3 – Fossil Fuel Fired Industrial and Commercial Equipment (Boilers and Heaters)
   Section 4C – NSPS Requirements for ‘CI’ ICE
   Section 5 – Specific Applicability

2) Specific Applicability for Item 5 of the equipment list:
   
   Condition 119: Permitted Facility Sources
   Condition 119.a: Permit-Wide Operations
   Condition 119.b: Fossil-Fuel Fired Industrial and Commercial Equipment (Boilers & Heaters)
   Condition 119.e.iii: New Source Performance Standards for CI ICE
   Condition 120: Local (New and Existing) Stationary Source Performance Standards.
   Condition 121: Exempt Sources.
ATTACHMENT 7

APPROVED O & M Plans for APC and CMS systems