I. GENERAL COMMENTS:

A. Company Information

1. Source Name: Becton, Dickinson and Company (BD)

2. Source Address: 7345 E. Valencia Road, Tucson, AZ 85747

B. Background

- Product Sterilization – SIC code 7389 – (NAICS 561910)

Ethylene oxide (EO) is a vital raw material used in large-scale chemical production with many diverse applications. 90%-95% of EO production is in the use as a raw feedstock in the manufacture of glycols, polymers, and various consumer and non-consumer organic chemicals, compounds, and their intermediates, to include detergents, thickeners, solvents, and plastics. Its primary use is for the synthesis of ethylene glycols, including diethylene glycol and triethylene glycol, which accounts for up to 75% of global EO consumption.

EO is also used in the manufacture of products, including but not limited to anti-freeze/coolants, hydraulic fluids and lubricants, detergents, paints and thinners, packaging materials and bottles, synthetic materials including polyesters, safety glass and rubber. Additional sources of EO can include byproducts of combustion, decomposition of plants and organic matter. While little is known of natural EO sources of monitored emissions, one of the known sources of this pollutant is as a result of fuel combusting processes.

EO is a human carcinogen and identified as a mutagenic, and teratogenic chemical. The EPA identified EO as a hazardous air pollutant (HAP) in §112(b) of the CAA, and pursuant to §112(d) of the CAA, on December 6, 1994, promulgated the National Emission Standard for Hazardous Air Pollutant (NESHAP), Subpart O standards for ethylene oxide commercial sterilization and fumigation operation(s) source category to protect the public health and welfare from potential emissions from this industrial source category. As provided in Title 17, Pima County DEQ was granted formal authority to administer Subpart O effective August 27th, 1999 by the Director of EPA Region 9 [64 Fed Reg. 34561 (June 28, 1999)].

Since 1938, EO has also been used as a sterilant/fumigant. For many decades EO has been used commercially in the production of medical equipment supplies and other miscellaneous sterilization -fumigation operations. EO’s use as a sterilant-fumigant makes up about 5%-10% of global consumption.

EO has a “non-ideal” bond angle with oxygen that gives the gas molecule a significant molecular angular strain making it unstable and highly reactive. It reacts with many nucleophiles and can open the \( \text{C} = \text{C} \) double ring bond of many organic compounds. Through these alkylation, addition, or substitution-type reactions, readily reacts with microorganisms at the cellular nuclear level. Its reactivity to cellular surfaces makes EO a very effective cytotoxic agent that can break down and cross cellular membranes. This reactive property of EO is exploited in modern commercial sterilization and fumigation operations to sanitize and/or sterilize medical instruments and supplies that may be otherwise too sensitive or incompatible to sterilize by using, heat, steam, radiation, or other techniques.

EO is the method of choice, and in most cases, the only viable option, for sterilization of a variety of medical devices including but not limited to: IV catheters, IV sets, blood collection devices, glass syringes, plastic syringes, procedural kits, stents, surgical preparation devices, surgical instruments, drug delivery devices, and auto-injectors.
The sterilization method is determined through a rigorous design process which includes review of material compatibility, product/packaging functionality, biocompatibility, and shelf life, in accordance with the requirements set forth by the Food and Drug Administration (FDA) and as outlined in consensus standards such as ISO/AAMI 11135-2015.

Sterilization by EO allows for the widest range of material compatibility, except for moisture and temperature-sensitive materials (>30 degrees C and/or <30% RH). Many single use devices (surgical devices, syringes, specialty catheters, pharmaceutical devices, etc) are sterilized with EO because they are too sensitive to be sterilized by any other method. Other sterilization modalities such as steam or radiation may cause undesirable effects on sensitive materials or cause excessive cross linking leading to discoloration and embrittlement. The effects of steam and radiation on anti-microbial coatings may preclude either modality. Multi-component kits may contain one or more devices which are sensitive to heat or radiation. Novel sterilization modalities are not yet proven efficacious or economically viable at the scale needed to support the global demand for sterile medical devices.

BD’s Environmental Health and Safety (EHS) standards ensure facilities are designed and operated with the highest level of process safety and environmental controls. The proposed facility will meet or exceed applicable federal, state and local EHS requirements. During facility operations, BD will employ best available emission control technology and state-of-the-art control systems to monitor and control process conditions and provide for continued safety of personnel and the community. Sterilization is a core competency for BD, which operates more than 20 sterilization sites globally.

Within the last few years, EPA’s air toxics program in coordination with state and local agencies has been gathering data on the ambient air levels of EO pollutant in various locations around the country and continues to review monitored EO background ambient air concentrations in order to further study EO sources and impacts on public health.

C. EO Emission Control Strategy

Process Emissions

The process emissions from the sterilization chambers and aeration vents are estimated to be in excess of 99% of the total facility emissions. Process emissions will be controlled by two LESNI® catalytic thermal oxidation (cat-ox) system(s) designed with a reduction efficiency exceeding 99%. These emissions and control systems are regulated by NESHAP Subpart O in addition to the voluntary emission cap. These controls will be performance tested within 180 days of startup and emissions of ethylene oxide continuously monitored using a CEMS, and as well as the catalyst bed temperature.

Fugitive Emissions

Potential fugitive emissions are expected from the gas room areas, sterilization areas, and as a result of the storage of the sterilized products. As part of the application, BD has proposed to use Advanced Air Technology® dry bed chemisorption control systems to control the fugitive EO from designated work areas and to effectively collect and limit these emissions.

The dry media bed systems will control fugitive EO emissions from the following facility areas:

- **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).
- **Area 3** – Work In Progress (WIP) & Post-Sterile Warehouse Areas. The aeration chambers are located in this area. Any fugitive from these chambers will be captured by the APCs located in Area 3. Emissions from the areas will be controlled by 4 separate dry bed systems.
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 averaged over 1 hour.

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 averaged over 1 hour.

Emissions from Area 3 (APC 5 – 8) 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 averaged over 1 hour.

As part of a required Operation and Maintenance (O & M) plan, the facility is required to provide a report demonstrating collection within a total enclosure to include the parametric monitoring of the negative air conditions and door openings using the data collected by the building management system. Also to be incorporated into the operation and maintenance plan is the requirement to document leaks from a LDAR (Leak Detection and Repair) program and any emergency room ventilations which will be accounted in facility cap below.

**Ethylene Oxide Emissions Cap**

To effectively limit the EO emissions from the facility, the Permittee has accepted a facility-wide EO emissions cap of 709 lb/yr. Compliance will be demonstrated by monitoring the average monitored emissions to the atmosphere from each APC stack/vent discharge point recorded by the CEMS each hour and tracking compliance on a 12-month rolling total basis, and to include any monthly leaks or ventilations monitored as part of a leak detection and repair (LDAR) program.

<table>
<thead>
<tr>
<th>Source/APC Designation</th>
<th>Control MFG</th>
<th>Description</th>
<th>Emissions Allotted under Cap</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ID’s 1-6 (APC 1 &amp; 2)</td>
<td>LESNI</td>
<td>Process Controls – Cat-Ox Abatement System(s)</td>
<td>≤ 1 PPMv, ~ 90 lb/yr (variable)</td>
<td></td>
</tr>
<tr>
<td>ID 7 (APC 3)</td>
<td>Advanced Air Technologies</td>
<td>Fugitive Area 1 - Gas Room Areas</td>
<td>≤ 13 lb/yr</td>
<td></td>
</tr>
<tr>
<td>ID 8 (APC 4)</td>
<td>Advanced Air Technologies</td>
<td>Fugitive Area 2 - Sterilization Chamber DLC Room Areas</td>
<td>≤ 79 lb/yr</td>
<td></td>
</tr>
<tr>
<td>ID’s 9-12 (APC 5 – 8)</td>
<td>Advanced Air Technologies</td>
<td>Fugitive Area 3 - WIP and Post Sterilization Storage Areas</td>
<td>≤ 527 lb/yr</td>
<td></td>
</tr>
</tbody>
</table>

1 Note: Total emissions allowed under the voluntary cap in Condition 46.a is monitored for compliance on a 12-month rolling total basis using hourly average emission rates from each APC discharge vent. Emissions are reduced to daily and monthly emissions for each APC and includes any additional monthly emissions documented from any discovered leaks or necessary emergency ventilations monitored by the Permittee or detected by the building management system. As part of the O & M plan the Permittee will submit a report demonstrating collection efficiency of the total enclosure and monitored parameters to establish effective collection.

The dry media used in Advanced Air Technologies controls reduces the EO concentration through the process of “chemi-sorption” with the media surface. The media is designed to provide approximately 250 lb of treatment capacity for each 900 lb of reactant at an efficiency of around 99%. The amount of EO that is chemi-sorbed in the dry beds is proportional to the amount of reactant in the dry bed and the life of the reactant. The sum total of dry media contained in the units is approximately 48,600 lbs and is estimated to have a capacity to control approximately 13,500 lb of EO at an efficiency of around 99%. It is estimated that the dry bed media will need replacement approximately every two years where towards the end of the media life the emissions will approach the limits of the permit.
The permit provides enforceable limits on total facility emissions by limiting the fugitive APC discharge vent concentrations and monitoring the total EO emissions from the facility calculated as a 12 month rolling total and sets out procedures to monitor the emission rates from the APC systems using a CEMS to calculate facility emissions accounting for any additional leaks external to the control areas. The actual emissions from each APC system using a CEMS will be continuously quantified as an average each hour from each APC and used to determine compliance with an emissions cap.

The facility has been designed around an annual EO usage of 225 tons of EO/yr. The emissions from each discharge vent will be monitored to determine the emissions from each APC (1–8). The permit includes approved test methods and procedures along with current reference methods, and the requirements for a CEMS system equipped with emissions measurement and flow monitors and determined hourly using a digital acquisition and handling system (DAHS). Compliance with the emission cap will ensure that potential impacts from the facility emissions adequately safeguards public health in accordance with current EPA guidelines. It is worth noting that actual emissions from the facility averaged over 2 or more years are estimated to be approximately half of the allowed permit limits, since the media of the dry beds will be replaced in two year cycles, and the cap is based on the maximum allowed EO concentrations from the dry beds systems that is only reached near the end sorbent media life cycle, whereas initially the beds will be more efficient and expected to have very low, near zero emissions. The monthly facility EO usage is a monitored parameter that can be used to track the remaining life, facility performance, and efficacy of the AAT dry bed media.

A model of the pollution impact from the facility prepared by Trinity Consultants, LLC accompanies the application on file with the Control Officer and demonstrates that the emissions allowed by the permit adequately safeguards the public health of residents and workers at businesses near the facility in accordance with current EPA’s guidelines.

D. Attainment Classification

BD is located in a region that is designated as in attainment for all conventional pollutants.

II. SOURCE DESCRIPTION

A. Process Description

1. Overview of Ethylene Oxide Sterilization Facility

BD is proposing to construct and operate an EO sterilization facility in Tucson on a 32.7-acre parcel. Figure 1 shows the location of the proposed facility.
Figure 1. Site Location

Figure 2. Preliminary Site Plan
Figure 3 Preliminary Facility Design

Figure 4 (Preliminary Facility Design with Point Discharges)
2. **Overview of Sterilization Process**

The EO sterilization process consists of the following main process steps:

a) **Preconditioning:** The product is exposed to controlled conditions of temperature and relative humidity in dedicated preconditioning cells to ensure homogeneity of the product with respect to temperature and humidity before being exposed to EO.

b) **Sterilization:** In this step, the product is exposed to EO inside a sterilization chamber under controlled conditions.

c) **Degassing/Aeration:** In two stages, EO is removed from the product within dedicated aeration cells under controlled conditions.

3. **Detailed Description of Ethylene Oxide Sterilization Process**

The following detailed description of the EO sterilization process is organized according to the steps outlined in Section I.D.2 (see Figure 5.) BD is proposing to install and operate six (6) sterilization lines, each with its own preconditioning cells, sterilization chambers, and aeration cells (2x per line). The sterilization chamber rooms, gas dispense room, and vaporizer room will be constructed as Damage Limiting Construction (DLC).

a. **Step 1: Preconditioning**

- Palletized product will be transferred from the receiving warehouse to the preconditioning cells to bring the product to a higher temperature using heat and humidity to condition the product and improve efficiency of the sterilization process.
- The cycle time for the preconditioning step is typically 6 to 10 hours, depending on the product.

b. **Step 2: Sterilization**

- After preconditioning, the product will be transferred automatically into the sterilization chamber from the preconditioning cell.
- At the beginning of each cycle, and before introduction of EO into the system, an automatic leak test will be performed. The leak test includes the dispensing system, vaporizer, gas dispense piping, and the sterilization chamber to ensure process integrity.
- During the first phase of the cycle, a deep vacuum is applied, followed by the injection of nitrogen to inert the chamber prior to injection of EO.
- The product will be exposed to EO (below atmospheric pressure) for the required exposure period.
- After the EO exposure phase, a series of “gas washes” will be performed in the chamber. The gas washes will involve the introduction of nitrogen and air to remove EO from the product.
- A nonflammable mixture of EO will be maintained during the cycles. The cycle time for the sterilization chambers will be approximately 6 to 10 hours, depending on the product.
- Exhaust air from the sterilization chambers will be ducted to the Lesni catalytic oxidation system for treatment prior to discharge to the atmosphere.
- Exhaust air from the rooms surrounding the sterilization chambers, gas dispense, and vaporizer areas will be treated with the Advanced Air Technologies® dry bed system prior to discharge to the atmosphere.
c. Step 3: Degassing/Aeration

- After completion of the sterilization cycle, the product is transferred from the sterilization chamber to the first aeration (degassing) cell, “Aeration A.” The aeration cells will be operated at elevated temperatures with multiple air circulations to remove residual EO from the product. The cycle time for the first aeration cell will be 6 to 10 hours, depending on the product.

- To further reduce any residual EO in the product, the product is transferred to the second stage heated aeration cell, “Aeration B.” The cycle time for this stage will also be 6 to 10 hours, depending on the product.

- Exhaust air from the aeration cells will be ducted to the LESNI® catalytic oxidation systems prior to discharge to the atmosphere.

- After completion of the second stage aeration, the product is moved to the sterile product warehouse.

- Exhaust air from the post-sterile warehouse (work in progress [WIP] warehouse) will be treated with the Advanced Air Technologies dry bed system prior to discharge to atmosphere.

**Figure 5 - Ethylene Oxide Sterilization Process**

4. Emission Controls

As described in the steps detailed in Sections II.D.3.a through c above, emissions of EO will be controlled with two types of systems, catalytic oxidation for process emissions, and dry bed absorption for fugitive emissions. The two systems are further characterized as follows:

- The two LESNI catalytic oxidation systems will have an expected control efficiency of at least 99.98 percent. These systems will control emissions from the sterilization chambers and aeration cells (three lines per system). The proposed control efficiency for the catalytic oxidation system exceeds the requirement identified in 40 CFR 63 Subpart O.

- Fugitive emissions from the sterilization chamber rooms, gas dispense and vaporizer rooms, will be controlled with Advanced Air Technologies dry bed systems. The overall removal efficiency for these systems will depend on the inlet concentration of EO but is expected to be greater than 90 percent. The outlet concentration is expected to be below 100 micrograms per cubic meter (μg/m3).
Note: These rooms will be provided with emergency ventilation that activates when 3 percent of the Lower Explosive Limit is detected to avoid a situation involving a fire or explosion.

- The post-sterile warehouse (WIP warehouse) will be controlled with Advanced Air Technologies dry bed systems. The overall removal efficiency for this system will depend on the inlet concentration of EO but is expected to be greater than 90 percent. The discharge concentration of EO from the WIP dry bed system is expected to be below 200 μg/m³. BD is proposing state-of-the-art air control systems and best available control technologies, far exceeding the requirements of 40 CFR 63 Subpart O, to ensure continued safety of personnel and the community.

5. Ancillary Equipment

To support the sterilization process, BD will install three (3) natural gas-fired boilers, each rated at 8.17 million British thermal units per hour (Btu/hr) heat input. BD will also install one 980-Brake horsepower (Bhp) diesel emergency generator and one 274-Bhp diesel fire pump. The emergency generator and fire pump will meet Tier 4 emission standards and will be subject to applicable requirements of 40 CFR 60, Subpart III, Stationary Compression Ignition Internal Combustion Engines.

B. Operating Capacity and Schedule

The plant and operations is currently planned for year round operations: 52 weeks a year, 365 days a year, 24 hours a day in three rotating work shifts.

C. Emissions Estimates/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.

<table>
<thead>
<tr>
<th>Source Type and Category</th>
<th>Conventional or Criteria Air Pollutants</th>
<th>NSPS or NESHAP Pollutant</th>
<th>HAP(s)</th>
<th>CO₂e</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PM₂.₅</td>
<td>PM₁₀</td>
<td>PM</td>
<td>NOₓ</td>
</tr>
<tr>
<td>Sterilization ¹</td>
<td>-</td>
<td>-</td>
<td>-</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 The total facility emissions allowed under a facility cap of 709 lb/yr that take into account fugitive EO collection efficiency, leaks and any emergency ventilation events. See Figure 4 and Table 2 below for details on emissions points and emission estimates.
## Table 2: Estimated Ethylene Oxide Sterilization Emissions

<table>
<thead>
<tr>
<th>Table 2: Estimated Ethylene Oxide Sterilization Emissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated Ethylene Oxide Use (lb/yr)</td>
</tr>
<tr>
<td>Percent of Use as Process Emissions</td>
</tr>
<tr>
<td>Lesni Catalytic Oxidizer Control Efficiency (Percent) b</td>
</tr>
<tr>
<td>Process Ethylene Oxide Emissions (lb/yr)</td>
</tr>
<tr>
<td>Gas Room Ethylene Oxide Discharge Concentration (ug/m³)</td>
</tr>
<tr>
<td>Gas Room Ethylene Oxide Discharge Concentration (ppm)</td>
</tr>
<tr>
<td>Exhaust Air Flow (cfm)</td>
</tr>
<tr>
<td>Exhaust Air Flow (scfm)</td>
</tr>
<tr>
<td>Gas Room Ethylene Oxide Emissions (lb/hr)</td>
</tr>
<tr>
<td>Gas Room Ethylene Oxide Emissions (lb/yr)</td>
</tr>
<tr>
<td>DLC Ethylene Oxide Discharge Concentration (ug/m³)</td>
</tr>
<tr>
<td>DLC Ethylene Oxide Discharge Concentration (ppm)</td>
</tr>
<tr>
<td>Exhaust Air Flow (cfm)</td>
</tr>
<tr>
<td>Exhaust Air Flow (scfm)</td>
</tr>
<tr>
<td>DLC Ethylene Oxide Emissions (lb/hr)</td>
</tr>
<tr>
<td>DLC Ethylene Oxide Emissions (lb/yr)</td>
</tr>
<tr>
<td>WIP Area Ethylene Oxide Discharge Concentration (ug/m³)</td>
</tr>
<tr>
<td>WIP Area Ethylene Oxide Discharge Concentration (ppm)</td>
</tr>
<tr>
<td>Exhaust Air Flow (cfm)</td>
</tr>
<tr>
<td>Exhaust Air Flow (scfm)</td>
</tr>
<tr>
<td>WIP Area Ethylene Oxide Emissions (lb/hr)</td>
</tr>
<tr>
<td>WIP Area Ethylene Oxide Emissions (lb/yr)</td>
</tr>
<tr>
<td>Total Ethylene Oxide Emissions (lb/yr)</td>
</tr>
<tr>
<td>Total Ethylene Oxide Emissions (tpy)</td>
</tr>
</tbody>
</table>

- Percent of ethylene oxide (EO) use resulting in process emissions is based on BD’s experience with the EO sterilization. The EPA currently estimates emissions using a higher emission factor. See Appendix A for a comparison of the PTE profile using EPA’s recommended industry emission factor and its effect on the potential to emit.

- Design control efficiency for the Lesni Catalytic Oxidation System to control process emissions.

- The AAT Dry Bed system will be used to control fugitive emissions from the gas room, DLC, and WIP.

Notes:

DLC = Damage Limiting Construction Rooms Emergency Ventilation; WIP = Work in Progress Areas
mg/m³ = (ppm) × (molecular weight Ethylene Oxide 44.05) / (24.45); 1 ppm = 1.8 mg/m³
lb/hr = (concentration in ppm) × (discharge flow rate in scfm) × (44.05 lb/mol) × (mol/385.32 scf) × 1/10⁶
× 60 min/hr/359 scf/mole ideal gas law constant corrected to 68°F and 1 atm = 385.32 scf/mole
III. REGULATORY HISTORY

None for the new proposed facility. BD operates more than 20 sterilization sites globally.

IV. APPLICABLE REQUIREMENTS

The facility is subject to Subpart O for the commercial sterilization source category in 40 CFR Part 63, NESHAP and Subpart III for the stationary compression ignition ICE source category in 40 CFR Part 60, NSPS. In addition the facility is subject a voluntary synthetic emission limitation and emissions cap in accordance with PCC 17.11.190.B and 17.13.070.B that is enforceable as a practical matter. The following is a summary of the Federal and Title 17 requirements of the Pima County Code which apply to the source:

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.
17.13.070 Establishment of an emission cap for Class II and III Permits.

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

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

Article IV - Public Participation for Class II and III permits (inclusive)
Article V – Fees for Class II and Class III Sources
17.13.240 Fees related to Class II and Class III permits.

Pima County Code Title 17, Chapter 17.14 – Activity Permits
Article I – General Provisions
17.16.040 Fugitive dust activity permits
17.14.080 Open burning permits.

Pima County Code Title 17, Chapter 17.16 – Emission Limiting Standards
Article I – General Provisions
17.16.010 Local rules and standards; Applicability of more than one standard.
17.16.020 Noncompliance with applicable standards.
17.16.030 Odor limiting standards.
Article II – Visible Emission Standards
17.16.040 Standards and applicability (includes NESHAP).
17.16.050 Visibility limiting standard.
Article III – Emissions from Existing and Nonpoint Sources (inclusive)
Article IV – New and Existing Stationary Source Performance Standards
17.16.130 Applicability
17.16.165 Standards of performance for fossil-fuel fired industrial and commercial equipment
17.16.530.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)
V. PERMIT CHANGES AND APPLICABILITY DETERMINATIONS

A. Permit and Permit Summary:

This part of the permit provides a summary of the location and description of the facility, its industrial classification, and the emission sources and controls used at the facility. It also introduces the procedures and conditions for which the permit may be revised or terminated, and a summary of emissions and limitations and introduction to Permit Terms and Conditions.

Note: Attachment 3, §§ 1 & 2: Comprise the General Conditions of the permit

B. § 1: General Provisions

Attachment 3, § 1 contains the general provisions that apply to all Class II and III air quality permits and Permittees in Pima County (Conditions 1 through 22).

C. § 2: Definitions

Attachment 3, § 2 of the permit contains applicable definitions from NESHAP Subparts A and O, and Title 17, and those specific to the permit.

Note: §§ 3 – 5: Comprise the Specific Conditions of the permit

D. § 3: Permit Applicability

Contains the general permit applicability, classification, and outline of the permitted sources and applicable permit sections to help organize the permit.

The statutory authority language in Condition 30 has been written to accommodate the implicit meaning within criteria used by the EPA in § 112 CAA to demonstrate an acceptable risk factor of 100-in-a-million to protect the health of the public for a lifetime of inhalation exposure. The permit allowances assure that the facility design is adequately protective of the public’s health and welfare demonstrated by emissions estimates and modeling submitted with the application on file with the Control Officer and site conditions at the time of issuance. This provision provides a means for the Administrator, Control Officer, Permittee, or citizens to require the permit to be enforced, reopened, or revised should there be any underlying change to the facility design, modifications or revisions to the current EPA policies, or NESHAP Subpart O provisions, or implicit findings accompanying the application and support documentation that are required or necessary to safeguard the public health.

E. § 4: Emission Limitations and Standards:

Local and State Requirements (Universal Control Standards)
40-42 Permit-wide limits, general control requirements, operation and maintenance requirements, 43 Opacity 44 Visibility

NESHAP Subpart O (Provided in Attachment 4 of the Permit)
45 Applicability
Except as provided in Condition 33, wherever the terms and Conditions in Attachment 4 of the permit are in disagreement with the provisions and intent of 40 CFR Part 63, Subparts A and O, the meaning in 40 CFR Part 63 shall prevail. Wherever used in the permit, Administrator shall mean the administrator of the EPA to distinguish such term from the Control Officer for those provisions reserved exclusively to the Administrator of the EPA.

45.a Permittee must comply with Table 1 of 40 CFR 63.360
45.b.i Standard for sterilization chamber and aeration room vents
Fugitive EO Emission Controls pursuant to PCC 17.11.190, 17.13.070, and 17.11.120.A.3.a

46 Voluntary Facility EO Emission Limit and Cap
Applicability: As of the date of issuance, the emission limits and voluntary facility emission limit and cap in this condition have been demonstrated to be adequately protective of the public health in accordance with findings published in EPA’s IRIS database, and modeling provided with the application on file with the Control Officer. The limits exceed current Federal CAA requirements for commercial sterilization facilities contained in NESHAP Subpart O.

46.a Facility EO Emission Cap
46.a.i Limit not to exceed: 709 lb of EO monitored as a 12-month rolling total
46.a.ii Formula to calculate the total Facility EO emission each month using hourly monitoring data and accounting collection within total enclosure and any additional reported leaks and emergency ventilation events.

46.b Operation Requirements for Advanced Air Technologies (AAT) fugitive APC controls
46.b.i Requirement to develop O & M Plan which is practically enforceable for approval by the Control Officer prior to operation. O & M plan may be revised without a re-opening of the permit.
46.b.ii O & M plan to include records procedures for the following:
46.b.ii.(a) Monitoring systems to include Chosen CEMS system to fulfill monitoring requirements, QA/QC procedures to include annual relative accuracy test audit, daily pressure drop, periodic visual inspection, and maintenance of the system(s).
46.b.ii.(b) Tracking of daily and monthly APC emissions, performance, applicable monitored building management system parameters, for each APC; documentation of daily pressure drop, amount of EO used, hours of operation, hours removed for maintenance, corrective actions, deviations or malfunctions and their duration.
46.b.ii.(c) A report of the design and parameters to be monitored by the Building Management System to include: all doors and openings closed except when in use, door status, operational status of APC, negative pressure indicators, and malfunction criteria to demonstrate total enclosure.
46.b.ii.(d) Development and implementation of leak detection and repair - LDAR program 30 days before first use of EO in sterilization chamber. To document any leaks and any necessary uncontrolled emergency ventilations.

Ancillary Operations

47 Ancillary Operations
(See Attachment 6 & GP for Fuel burning Equipment) for applicable requirements.

F. § 5: Compliance Determination

§ 5a Monitoring and Recordkeeping Provisions

Local and State Requirements

50 General Recordkeeping Requirements
All records required to be maintained in accordance with the general provisions.

51. Permit-Wide Provisions
51.a – g Contains the provisions requiring maintenance of records for operating limits and parameters when specified in the equipment list and monthly, 12-consecutive month totals or averages of applicable operating parameters and limits. Requires maintenance of visible emissions records and determinations (when applicable), equipment opacity checks (if required); Documentation of any required activity permits and associated records. Contains references to monitoring requirements in the General Provisions, and Attachment 7 O & M plan.

52. NESHAP Subpart O (in Attachment 4 of the Permit)
52. Initial performance testing pursuant to Table 1 of 40 CFR 63.360
52.a Performance Testing required within 180 days of startup.
52.b Initial Compliance
52.c Continuous Compliance with the oxidation temp and work practice standards.
52.d Monitoring Requirements – CMS LESNI CEMS & Oxidation Temperature
   Written startup, shutdown, and malfunction plan for CMS
52.e Recordkeeping Requirements
   Additional CMS recordkeeping requirements
   Records of compliance tests, data analysis and if catalyst replacement.

53. Voluntary Facility EO Limits and Cap per PCC 17.11.190, 17.13.070 & 17.11.120.A.3.a
53.a Facility EO Emissions Cap Monitoring
53.a.i General monitoring provisions of APC 1-8 each calendar day
53.a.i(a) Installation of required monitoring devices to startup; Data collection requirements apply
   within 180 days of startup; deviation reporting; invalid and missing data handling
53.a.i(b) Emission rate determination; CEMS definition; determination of emissions each hour, day,
   and month used towards compliance with emission cap.
53.a.i(c) Installation of pitot-type flow monitoring to calculate mass of emissions each hour.
52.a.ii Specific Monitoring and Reporting Criteria for APC 1 & 2
53.a.iii Specific Monitoring and Reporting Criteria for APC 3 – 8
53.a.iv Data Handling Requirements
53.b Recordkeeping requirements; monthly EO usage, Facility EO Cap Spreadsheet, Copy of
   current O & M plan with required elements, files of parameters monitored for plan
   elements, maintenance logs, deviation from parameters, duration and corrective actions
   taken.

§ 5b Testing Provisions

54. NESHAP Subpart O
54.a-e Performance Testing Provisions (Note: RATA test may done in lieu of performance test)
55. Fugitive EO Emission Controls pursuant to 17.11.190, 17.13.070, & 17.11.120.A.3.b
55.a Prior to startup requirement to install calibrate and maintain dedicated CEMS to monitor
   emissions from APC 1 -8;
55.b CEMS QA procedures and relative accuracy (RA) testing requirements. RATA may be
   used in lieu of any performance test required by permit.
55.c Reference and other methods and procedures approved by the Control Officer for
   measuring and monitoring EO concentrations for compliance with permit.
55.d Notification requirement for periodic performance testing
55.e Waiver to allow summary performance reporting in lieu of full written test reports by
   mutual agreement
55.f Requirement to maintain full written reports or monitoring data of any onsite testing
   conducted in accordance with this Condition.

§ 5c Reporting Provisions

56. Permit-Wide Provisions
56.a Periodic Reports
56.a.i Annual Summary Reports of Required Monitoring
   (a) 12-month rolling total of Facility EO emissions in Spreadsheet
   (b) For APC 1 & 2 emissions rates showing compliance monitoring and data collection
       summary.
   (c) For APC 3 – 8 emission rates showing compliance monitoring and data collection summary
       (i) Summary and duration of deviations and malfunctions from permit requirements, APC
           unit downtime as a percentage, corrective actions required, to restore APC or Building
           Management System parameters.
   (d) Annual Log of facility changes in accordance with Condition 9.d.v.
56.a.ii Annual NESHAP Subpart O reports (See Attachment 4)
56.b Special Reporting and Notifications
57. NESHAP Subpart O
   57.a.i Performance Test Reports
   57.a.ii CMS Performance Evaluation (if requested)
   57.a.iii Annual Excess Emissions and Continuous Monitoring System
       CMS Performance Summary Reports
   57.b Reports submittals to Control Officer and Administrator as required by 40 CFR 63.10.
   57.c Electronic submittals allowed if acceptable to both Permittee and Control Officer
   57.d Content and Submittal dates
   57.e Applications for approval of construction or reconstruction of new or existing source
   57.f Notification requirements per 40 CFR 63.9
   58. Requirement to post a monthly summary report of the average monitored daily and monthly
       EO emissions and the 12-month Facility Emission Cap Spreadsheet on Permittee’s hosted
       webpage to allow such information to be made available to the public.

VII. PERIODIC MONITORING

The permit requires periodic monitoring in accordance with an approved O & M plan, periodic testing of
the CEMS, and periodic reports of required monitoring to be submitted on an annual basis.

VII. INSIGNIFICANT ACTIVITIES.

The insignificant activities defined in PCC and as determined by the Control Officer for the facility are
listed in Attachment 2 and Table 1 of this TSD.

VIII. IMPACT TO AMBIENT AIR QUALITY

An impact study was prepared by Trinity Consultants using local weather data to model impacts in the
surrounding areas when limiting the emissions to the EO emissions cap provided in the permit. The results
show that the modeled emissions are adequately protective of the public health over a lifetime of
inhalation exposure with the highest modeled impact in the nearest residential area showing levels 5 times
less than the allowable EPA ambient air quality levels of 2.0 x 10-2 micrograms/cubic meter. Levels near
the property fence-line have also been evaluated for safety of employees at nearby facilities and show
these levels also conform to EPA guidelines.\footnote{The EPA explained its approach for the consideration of non-residential impacts in the “Risk Assessment Report for the Sterigenics Facility in Willowbrook, Illinois.” See the final paragraph of Section 2.3 on page 16 of the report EPA Region 9 Comments BD – Ethylene Oxide Sterilization Facility 5 available here: https://www.epa.gov/il/risk-assessment-report-sterigenics-facility-willowbrook-il.}

IX. CONTROL TECHNOLOGY DETERMINATION

PCC 17.16.530(B) incorporates by reference the NESHAP for source categories in Subpart A (General
Provisions) and Subpart O (Ethylene Oxide Emissions Standardizations for Sterilization Facilities).
Section 63.8(c) of subpart A includes monitoring requirements for source categories and requires CMS
(Note: Permittee has opted to use catalyst oxidation temperature as the chosen CMS). Subpart O has
monitoring requirements that apply to EO facilities. The general monitoring requirements in Subpart A
apply to EO facilities “according to the applicability in Table 1 of § 63.360.” Additional fugitive controls
to be installed as provided in the application with the proposed limits demonstrate that safe ambient air
concentration levels will be maintained in accordance with the current EPA risk factors in the IRIS
database and in anticipation of any promulgation or revisions to the NESHAP Subpart O rule.
X. EXCLUSION OF PCC PARTICULATE MATTER DISCHARGE RATE STANDARDS

The applicable PCC rules for the maximum particulate discharge rates are not normally included for Class II and III area source permits as explained below.

- For particulate matter sources, the calculated maximum particulate matter discharge rate, as provided in Title 17, yields maximum rates that far exceed the emissions expected from most typical area sources. For example, a 200 ton/hour process source, which is typical for an average construction aggregate screening operation, would be limited to a maximum discharge rate of 40.4 lbs/hour or 177 tons/year. This limit far exceeds estimated emissions from typical sources and the source is far more likely to exceed opacity and visibility limiting standards well before reaching this limit.

With regard to fuel burning equipment, PCC 17.16.165.C limits the emissions of particulate matter from commercial and industrial fossil-fuel fired equipment (including but not limited to boilers). This limit is not normally included in permits because allowable emissions are consistently over an entire order of magnitude higher than EPA AP-42 estimated potential emissions. The chart below, illustrates the point.

![Comparison of Emissions of PM-10 for Boilers: PCC Allowable vs AP-42 Estimated](chart.png)

Comparative Chart of Allowable Particulate Emissions Under Pima County Code, Title 17, and Estimated Potential Emissions based on EPA AP-42 Estimates for External Combustion Sources. Allowable emissions are consistently over ten times estimated potential emissions. Therefore, it is not necessary to include the standard in the permit explicitly, but by reference in this TSD and the applicable regulations in Attachment 1 of the permit.
Attachment 1
Emission Factors & PTE

1. Sterilization Operations Process EO Emissions (APC 1 & 2)

<table>
<thead>
<tr>
<th></th>
<th>APC 1</th>
<th>APC 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAP &amp; VOC (EO):</td>
<td>0.005 lb/hr</td>
<td>0.005 lb/hr</td>
</tr>
</tbody>
</table>

2. Sterilization Operations Fugitive EO Emissions (APC 3 – 8)

<table>
<thead>
<tr>
<th></th>
<th>APC 3</th>
<th>APC 4</th>
<th>APC 5</th>
<th>APC 6</th>
<th>APC 7</th>
<th>APC 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAP &amp; VOC (EO):</td>
<td>0.0015 lb/hr</td>
<td>0.009 lb/hr</td>
<td>0.015 lb/hr</td>
<td>0.015 lb/hr</td>
<td>0.015 lb/hr</td>
<td>0.015 lb/hr</td>
</tr>
</tbody>
</table>

3. Boilers and Generators

PM2.5 1.02 x 10^{-4} lb/hr
PM10 1.03 x 10^{-4} lb/hr
CO 1.2 x 10^{-3} lb/hr
NOx 1.52 x 10^{-3} lb/hr
SO2 7.99 x 10^{-6} lb/hr
VOC’s 9.25 x 10^{-5} lb/hr
HAPs 3.54 x 10^{-5} lb/hr

Total Potential to Emit (Tons/year)

<table>
<thead>
<tr>
<th>Source</th>
<th>PM$_{10}$</th>
<th>PM$_{2.5}$</th>
<th>CO</th>
<th>NO$_x$</th>
<th>SO$_2$</th>
<th>VOC$_s$</th>
<th>HAPs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization Operations (EO)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.36</td>
<td>0.36</td>
</tr>
<tr>
<td>Boilers and Generators</td>
<td>0.82</td>
<td>0.82</td>
<td>4.33</td>
<td>1.21</td>
<td>0.09</td>
<td>0.60</td>
<td>0.20</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>0.82</strong></td>
<td><strong>0.82</strong></td>
<td><strong>4.33</strong></td>
<td><strong>1.21</strong></td>
<td><strong>0.09</strong></td>
<td><strong>0.96</strong></td>
<td><strong>0.56</strong></td>
</tr>
</tbody>
</table>
### PROCESS AND FUGITIVE POTENTIALS

<table>
<thead>
<tr>
<th>Emission Factors</th>
<th>Process Emissions (APC 1 &amp; 2)</th>
<th>Fugitive Emissions (APC 3 - 8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry</td>
<td>EPA</td>
<td>Industry</td>
</tr>
<tr>
<td>99.5%</td>
<td>99.32% Process Potential (1 - Fugitive Potential)</td>
<td>99.9%</td>
</tr>
<tr>
<td>43750</td>
<td>44000</td>
<td>2.350</td>
</tr>
<tr>
<td>99.97%</td>
<td>99.97% Reduction Efficiency (Actual System)</td>
<td>0.92</td>
</tr>
</tbody>
</table>

### DESIGN CONSIDERATIONS

<table>
<thead>
<tr>
<th>Expected Process Emissions from LDAI System (lbs)</th>
<th>1/2 Fugitive Emissions (lbs) from Dry Bed System APC 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 lbs/yr</td>
<td>1/2 Fugitive Emissions (lbs) from Dry Bed System APC 3</td>
</tr>
<tr>
<td>65.75 lbs/yr</td>
<td>1/2 Fugitive Emissions (lbs) from Dry Bed System APC 8</td>
</tr>
<tr>
<td>65.75 lbs/yr</td>
<td>1/2 Fugitive Emissions (lbs) from Dry Bed System APC 3</td>
</tr>
</tbody>
</table>

**Note:** According to the MFG literature, each 900 lbs of media is able to chemically break approximately 260 lbs of CO at a 99% reduction efficiency. This would provide a capacity to absorb 6200 lbs of CO over approximately two years of life expectancy based on the weight of media in the installed APC units (21,000 lbs). The capacity is between the range of estimated fugitive CO using the two fugitive emission factors (industry and EPA) at 1.0% reduction efficiency for the control system would be around 90%. At 90% reduction efficiency, media MFG estimates the media could absorb ~10,000 lbs of CO. So, amount of media is sized to absorb between 20,000 - 6,000 lbs of CO with a control efficiency ranging between 90% and 99%. With an installed weight of 21,000 lbs of chemisorbent media, the control efficiency and sizing (weight) of the dry bed is adequately sized to maintain CO concentrations to levels below the permit limits based on anticipated or potential fugitive emissions loading.

### APC 1 & 2 Controlled Emissions Potential

<table>
<thead>
<tr>
<th>Emission Rate</th>
<th>APC 1 &amp; 2 Controlled Emissions Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.05%</td>
<td>lbs/yr</td>
</tr>
</tbody>
</table>

### APC 3 - 8 Controlled Emissions Potential

<table>
<thead>
<tr>
<th>Emission Rate</th>
<th>APC 3 - 8 Controlled Emissions Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.07%</td>
<td>lbs/yr</td>
</tr>
</tbody>
</table>

### Uncontrolled Emission Rate LDAI

<table>
<thead>
<tr>
<th>Uncontrolled Emission Rate LDAI</th>
<th>APC 3 - 8 Uncontrolled Emission Rate (% Emissions Factor)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20.8 lbs/hr</td>
<td>Uncontrolled Emission Rate % Emissions Factor</td>
</tr>
</tbody>
</table>

### Excess Emission (709 lbs) |

| Excess Emission (709 lbs) | 18 hrs |

### 0.1% Methane Time = Exceedance 700 B = 36 hours out of control

<table>
<thead>
<tr>
<th>Time to Exceedance</th>
<th>0.1% Methane Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>653.05 lbs</td>
<td>21.14 hrs</td>
</tr>
</tbody>
</table>

### For APC 5 & 8, 0.1% Methane Time (combined) = Exceedance 600 B = 3614 hours = 67 days for each APC. Note units 5 and 8 to small to consider. Le will not exceed 600 lbs. If duration of downtime exceeds 67 days: exceedance. Vs. 117 days using industry factor.
Uncontrolled Emission Rates For purposes of Malfunction

The following rates \(^1\) for purposes of calculating uncontrolled emissions for the reporting of excess emissions during malfunction and downtime for subject APC, while the facility is otherwise operating (blower on, with no controls) or wherein no data is available from both monitored parameters (See Condition 53.a.ii(c), and 53.a.iii(c) of the permit). Where malfunctions are reported as a percentage of operating hours, that portion of the facility emissions may be calculated using the following uncontrolled emission rates. Where there may be more than one unit malfunctioning (uncontrolled) at the same time the rates are additive for each device during such periods.

<table>
<thead>
<tr>
<th>APC</th>
<th>LB/HR</th>
<th>LB/Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>25.46</td>
<td>611</td>
</tr>
<tr>
<td>2</td>
<td>25.46</td>
<td>611</td>
</tr>
<tr>
<td>3</td>
<td>0.010</td>
<td>0.25</td>
</tr>
<tr>
<td>4</td>
<td>0.062</td>
<td>1.49</td>
</tr>
<tr>
<td>5</td>
<td>0.095</td>
<td>2.28</td>
</tr>
<tr>
<td>6</td>
<td>0.095</td>
<td>2.28</td>
</tr>
<tr>
<td>7</td>
<td>0.095</td>
<td>2.28</td>
</tr>
<tr>
<td>8</td>
<td>0.095</td>
<td>2.28</td>
</tr>
</tbody>
</table>

\(^1\) Derived using an EPA emission factor of 0.88% of usage for Fugitive (APC 3-8) and 99.12% for process emissions)

Uncontrolled Emission Rate as a result of an event which triggers an emergency room ventilation shall be calculated by estimating the amount emitted by release of 1 room volume at the average EO room concentration of \(1/2\) of the 3% of LEL alarm value (450 PPM), unless data is available to more accurately determine the release or leak quantity upon investigation.
ATTACHMENT 2: SOURCE APPLICABILITY

(Unless otherwise noted, references are to Title 17 of the Pima County Code (PCC), Arizona Revised Statues (ARS), Arizona Administrative Code (AAC.), or the Pima County State Implementation Plan (SIP). Underlined text are hyperlinked Conditions within this attachment, or to external websites containing the referenced provision.)

1. Permitted Facility Sources

The Conditions in the permit apply to the following source categories, affected facilities, equipment, emission sources, installations, activities and operations at the facility.

a. Permit-Wide Requirements Conditions 40 – 44, 50, 51, 56  
   [Federally and Locally Enforceable Conditions]

   Except as provided in Condition 3 of this attachment, the Conditions apply to the facility and all sources of air contaminants at the facility. Contains facility-wide limits, and standards for general control, operation and maintenance, general materials handling, gaseous and odorous materials, opacity (optical density), and visibility limitations. In addition, it contains provisions for recordkeeping and reporting to demonstrate compliance with the permit and general provisions, facility-wide limits, visible emissions (VE) determinations and opacity checks (when prescribed)


b. NESHAP Subpart O; Conditions; Condition 45, 52, 54, 57

   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 and Table 1 of § 63.362 – Standards for Ethylene Oxide Commercial Sterilizers and Fumigators.

c. Fugitive EO Emission Control; Condition 46, 53, 55, 56

   The Conditions apply to the affected process and fugitive emission vents from the referenced APC systems in accordance with the application on file with the Control Officer and as listed in Table 1 of Condition 46, and the equipment list in Attachment 2. The provisions are voluntary and federally enforceable in accordance with Title 17 of the PCC. The General Provisions in § 1 of the permit also apply.

   As of the date of issuance of the permit, the emission limits contained in these Conditions have been derived from the application and demonstrate adequate protection of the public health in accordance with findings published in EPA’s IRIS database and modeling submitted with the application on file with the Control Officer. The limits in this Condition exceed current Federal CAA requirements for commercial sterilization facilities contained in NESHAP Subpart O. Should any conditions at the facility, or any federal, state, or local rules or findings change such determination, the permit is required to be reopened and the permit revised.

   Prior to initial startup of the source, the Permittee is required to submit an O & M plan in accordance with Condition 42.c to verify proper operation and integrity of monitoring systems and APC units and to incorporate periodic inspection forms, and proposed records to document the monitoring and operating parameters of the APC, maintenance logs, deviations and malfunctions from operating parameters, times removed from service, and any corrective actions taken to restore units or parameters to their proper function. These provisions include provisions establishing the areas as permanent total enclosures and include provisions for incorporating an LDAR program to monitor and account for facility leaks.

   As required by the O & M plan, the Permittee shall demonstrate compliance with the plan criteria to establish practically enforceable monitoring and recordkeeping provisions for the fugitive EO emissions including the building monitoring system to monitor proper fugitive emission collection.
d. Additional Ancillary Sources and Operations

See Attachment 2A of this TSD for the specific applicability for any applicable additional ancillary sources or operations listed in the permit equipment list.

i. When added to the facility and indicated in the equipment list, the Permittee shall follow the applicable terms and Conditions contained in a separate air quality general permit (GP) issued by the Control Officer or the Director and in accordance with Title 17 of the PCC for such sources as provided in an Attachment to the permit. This shall afford the Control Officer the ability to streamline the permitting and revision process for Permittees that may desire to install and operate such sources and facilities within a defined source class, having identical requirements and Conditions, and for the purpose of accommodating rule changes, and maintenance of emission inventories for such sources within Pima County.

ii. Notwithstanding such additional ancillary sources that may be covered under this permit, the Permittee shall only be subject to the fees under Condition 8 of the permit and only be required to submit facility changes and applications to revise or renew the permit in accordance with Condition 1 of the permit.

iii. The specific terms and Conditions contained in the GP’s issued by the Control Officer as listed below are hereby incorporated into the permit and shall apply to such emission sources should the Permittee desire to add such a source to the facility in the future and when indicated in the equipment list in Attachment 2 of the permit.

(a) General Air Quality Permit for
   *Perchloroethylene Dry Cleaners, PDEQ Permit # 6099, Issued June 12, 2015*;
   Download links: [Permit] || [Application] || [Technical Support Document]

(b) General Air Quality Permit for
   *Human an Animal Crematories, PDEQ Permit #6085, Issued May 13, 2015*;
   Download links: [Permit] || [Application] || [Technical Support Document]

(c) General Air Quality Permit for
   *Gasoline Dispensing Facilities, PDEQ Permit # 6096, Issued October 17, 2020*
   Download links: [Permit] || [Application] || [Technical Support Document]

(d) General Air Quality Permit for
   *Non-Metallic Material Handling Facilities, PDEQ Permit #6210, Issued April 24, 2017*
   Download links: [Permit] || [Application] || [Technical Support Document]

(e) General Air Quality Permit for
   *Plating, Anodizing & Polishing Facilities, PDEQ Permit #6144, Issued December 3, 2015*
   Download links: [Permit] || [Application] || [Technical Support Document]

(f) General Air Quality Permit for
   *Fuel Burning Equipment, PDEQ Permit # 6205, Issued January 5, 2017*
   Download links: [Permit] || [Application] || [Technical Support Document]

(g) General Air Quality Permit for
   *Soil Vapor Extraction Units (SVEU), AZDEQ Permit #102, Issued June 24, 2016*
   Download links: [Permit] || [Application] || [Technical Support Document]

iv. Should any of the incorporated GP provisions in Condition 1.d.iii of this attachment be changed as a result of a renewal or reopening of a GP, the Permittee has been granted a permit shield in accordance with PCC 17.11.080 for compliance with such terms and Conditions until such time as the Permittee renews this permit. The Control Officer shall provide notice to the Permittee of any resulting changes and if the Permittee is required to revise the permit per Conditions 14.a.ii or iii of the permit.
v. For each ancillary source identified in the equipment list in Attachment 2 of the permit, the Permittee shall follow the specific Conditions in the above listed GP’s that apply to such sources. The applicable referenced permit sections and Conditions for such sources shall be provided as an Attachment to the permit.

vi. Any GP Condition requiring compliance with facility-wide and general provisions of the GP shall be construed to require compliance with the permit provisions in § 1: General Provisions and § 4: Facility-Wide Operations.

vii. Any GP Condition with throughput or operating hour limitations shall be additionally restricted or limited to those operating limitations provided as operating limitations in the equipment list in Attachment 2 of the permit.

viii. Condition 29 of the permit (shall apply to any specific Condition(s) in a GP that are in conflict with any provision in the permit.

2. Portable Sources

   [PCC 17.11.100 & 110]
   [Locally Enforceable Conditions]

a. Portable Sources Requiring a Permit

   The Permittee shall comply with the following: [PCC 17.11.100 & 110]

   i. Permitted portable sources transferred from one location to another shall be required to submit a notice to the Control Officer, and if applicable, the Director as described in Condition 9.b.iv of the permit. The Permittee shall submit such notices to the address provided in Condition 11 of the permit.

   ii. A portable source that requires a permit pursuant to PCC 17.11.090 that will operate for the duration of its permit in Pima County shall obtain a permit from the Control Officer. Should such source desire to locate and operate outside the County, the Permittee shall comply with Condition 3 of the permit.

   iii. Portable sources covered under a separate permit and transferred to a facility covered under the permit must comply with the applicable limit in Condition 36.b of the permit in addition to any Conditions in a permit issued to such portable source. Following a review of the transfer notice required by Condition 9.b.iv of the permit, the Control Officer may require the Permittee to submit a significant permit revision as specified in Condition 14.a.iii of the permit prior to operation of the relocated portable source.

b. Portable Sources Not Requiring a Permit

   i. Portable sources, including transportable non-road engines, located or stored at the facility, that are not required to be permitted in accordance with Title 17 of the PCC, and that have a potential to emit in excess of the insignificant activity levels in Table 1 of this attachment, may be required to demonstrate their status as a portable source upon request by the Control Officer. The Permittee shall maintain records for such sources documenting when the portable source was moved to its current location from a previous location or storage area. The Permittee may use the sample Portable Source Location log in Attachment 3 of this TSD for purposes of documenting the status of such portable sources. For the purpose of this provision, the Control Officer has determined that sources that can be moved by hand or have a combined potential to emit (PTE), without controls, less than 10% of the major source threshold to be insignificant activities not requiring the maintenance of a portable source location log.

   ii. The owner or operator of any portable source of air pollution which burns any material, except natural gas, shall keep complete records of the materials used as fuel.

   iii. The owner or operator of any portable source which incinerates any material shall keep complete records of all materials incinerated.
3. **Exempt Sources**

   a. **Agricultural Equipment**

   The Specific Conditions contained in the air quality permit shall not apply to agricultural equipment used in normal farm operations, unless their operation without a permit would result in a violation of the Act. [PCC 17.12.090.C.3]

   [Locally Enforceable Condition]

   b. **Motor Vehicles**

   The Specific Conditions contained in the air quality permit shall not apply to emissions from motor vehicles. *Motor Vehicles* herein means any self-propelled vehicle designed for transporting persons or property on public highways.

   c. **Mobile Sources**

   Except as provided in PCC Chapter 17.16 § 450, 460, 470, and 480 which applies to off-road machinery, heater planer units, roadway and site cleaning machinery, and asphalt or tar kettles, the Conditions contained in this permit shall not apply to mobile sources.

4. **Insignificant Activities**

   For the purpose of this permit, equipment or operations in Table 1 of this attachment below have been determined by the Control Officer, because of their size or production rate, to be de-minimus emission sources and or insignificant activities in accordance with PCC 17.04.340.A.114. For other insignificant activities the Permittee shall keep a log of insignificant activities per Condition 14.b.i of the permit.
<table>
<thead>
<tr>
<th>Description</th>
<th>Maximum Rated Capacity</th>
<th>Fuels Used or Materials Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Landscaping, building maintenance, or janitorial services.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2) The following Gasoline and Volatile Organic liquid (VOL) Storage Tanks:</td>
<td>V ≤ 10,000 gal.</td>
<td>Gasoline or VOL</td>
</tr>
<tr>
<td>- All gasoline storage tanks less than 250 gallons capacity provided they</td>
<td></td>
<td></td>
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<tr>
<td>otherwise comply with 40 CFR 59, Subpart F,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Gasoline storage tanks greater than 250 gallons and less than 10,000</td>
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<td></td>
</tr>
<tr>
<td>gallons with a throughput less than 1000 gallons per month, provided</td>
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<td></td>
</tr>
<tr>
<td>such tanks are equipped with a submerged filling device, or acceptable</td>
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<td></td>
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<tr>
<td>equivalent, for the control of hydrocarbon emissions in accordance with</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCC 17.16.230.B</td>
<td></td>
<td></td>
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<tr>
<td>- Gasoline storage tanks less than 10,000 gallons capacity provided they</td>
<td></td>
<td></td>
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<tr>
<td>are not otherwise required to meet NESHAP Subpart 6C.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- All volatile organic liquid (VOL) tanks less than 10,000 gallons</td>
<td></td>
<td></td>
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<tr>
<td>provided they comply with Condition 38.a of the permit.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2a) **The following tanks located at the facility:**

   **Samsco Evaporator System Tanks:** TK-1 – 1000 gal.; TK-2 – 6500 gal.; TK-3 – 6500 gal.; SEP – 0 – 52 gpm.

3) Petroleum liquids storage tanks and VOL storage tanks with the following volume (V) capacities and stored liquid vapor pressure ranges, provided that petroleum liquid storage vessels maintain a file of the each type of petroleum liquid stored, dates of storage, and the typical Reid vapor pressure of each type of petroleum liquid stored, and for those petroleum liquids storage tanks > 40,000 gallons the average monthly storage temperature and true vapor pressure is determined and recorded. Statements from the fuel supplier showing the fuels delivered to such vessels shall be acceptable.

<table>
<thead>
<tr>
<th>Cutoff for monitoring per PCC 17.16.230.E.2 and/or NSPS Subpart Kb:</th>
<th>All sizes</th>
<th>Petroleum liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Petroleum Liquids with a max. true vapor pressure &lt; 0.50 psia (3.5 kPa) under actual storage conditions.</td>
<td></td>
<td>Petroleum liquid</td>
</tr>
<tr>
<td>b) VOL with a max true vapor pressure &lt; 2.17 psia (15 kPa) under actual storage conditions</td>
<td>V &gt; 10K gal.</td>
<td>VOL</td>
</tr>
<tr>
<td>c) VOL with a max true vapor pressures &lt; 0.5 psia (3.5 kPa) under actual storage conditions</td>
<td>V &gt; 40K gal.</td>
<td>VOL</td>
</tr>
</tbody>
</table>

4) Diesel, Fuel Oil, or Jet A storage tanks

5) Batch mixers. 5 cu ft. or less

6) Wet sand and gravel production facilities whose permanent in-plant roads are paved and cleaned to control dust. This does not include activities in emissions units which are used to crush or grind any nonmetallic minerals.

7) Hand-held or manually operated equipment used for buffing, polishing, carving, cutting, drilling, machining, routing, sanding, sawing, surface grinding, or turning of ceramic artwork, precision parts, leather, metals, plastics, fiberboard, masonry, carbon, glass, or wood. Including the following:

   - Facility-Wide small commercial abrasive blasting cabinets provided they are equipped and maintained with filtration control devices. For the purpose of this activity, small cabinets are defined to be cabinets not designed to allow persons inside the cabinet while in use.

8) Powder coating operations
**Table 1: Insignificant Activities (Continued)**

<table>
<thead>
<tr>
<th>Description</th>
<th>Maximum Rated Capacity</th>
<th>Fuels Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>9) Internal combustion (IC) engine-driven compressors, IC engine-driven</td>
<td></td>
<td></td>
</tr>
<tr>
<td>electrical generator sets, and IC engine-driven water pumps used only</td>
<td></td>
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<tr>
<td>for emergency replacement or standby service.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Note:</strong> Portable or temporary internal combustion engines (ICE) or non-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>road engines that operate, or are planned for operation, at a fixed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>location for more than 12 months shall be subject to stationary source</td>
<td></td>
<td></td>
</tr>
<tr>
<td>permitting requirements. Portable ICE used or located at a facility,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>may be required to keep records as provided in Condition 2.b of this</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attachment to document when the ICE is transferred to or from the</td>
<td></td>
<td></td>
</tr>
<tr>
<td>facility, or alternate locations at the facility, and/or storage areas</td>
<td></td>
<td></td>
</tr>
<tr>
<td>in order to establish that the unit is not subject to stationary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>permitting requirements. Portable ICE that are used to replace a</td>
<td></td>
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</tr>
<tr>
<td>stationary ICE at a fixed location and intended to perform the same or</td>
<td></td>
<td></td>
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<tr>
<td>similar function shall include the time period of both engines to</td>
<td></td>
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<tr>
<td>determine the consecutive time period for purposes of stationary ICE</td>
<td></td>
<td></td>
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<tr>
<td>permitting. Notwithstanding the stationary ICE permitting requirement,</td>
<td></td>
<td></td>
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<tr>
<td>a portable ICE shall not be required to meet the NSPS or NESHAP ICE</td>
<td></td>
<td></td>
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<tr>
<td>standards for stationary sources when used as an emergency replacement</td>
<td></td>
<td></td>
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<tr>
<td>or as a standby unit, while the facility effects repairs, or while</td>
<td></td>
<td></td>
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<tr>
<td>ordering a replacement unit, unless the Permittee intends for the</td>
<td></td>
<td></td>
</tr>
<tr>
<td>replacement portable ICE to be permanent. Portable ICE used to replace</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a stationary permitted ICE shall be limited by the same run hour limits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(if any) applicable to the replaced unit at that facility location.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The balance of the permitted allowable run hours allotted to the</td>
<td></td>
<td></td>
</tr>
<tr>
<td>stationary ICE shall continue to accrue with the operation of the</td>
<td></td>
<td></td>
</tr>
<tr>
<td>replacement unit. When used for this specific purpose, the permittee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>shall be required to keep records of the run hours and emissions of the</td>
<td></td>
<td></td>
</tr>
<tr>
<td>portable ICE for emission inventory purposes.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10) Lab equipment used exclusively for chemical and physical analyses.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11) Trivial activities as provided in PCC 17.04.340.a.237 a through xx.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12) The Control Officer has deemed the following portable sources located</td>
<td></td>
<td></td>
</tr>
<tr>
<td>at a facility and having a combined capacity less than the amount in</td>
<td></td>
<td></td>
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<tr>
<td>its FBE class, as listed below, to be an insignificant activity per</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Condition 2.b of this attachment, and not requiring documentation to</td>
<td></td>
<td></td>
</tr>
<tr>
<td>demonstrate their portable source status:</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Fuel Burning Equipment (FBE) Class</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diesel Fired Engines(^1)</td>
<td>75 hp</td>
<td></td>
</tr>
<tr>
<td>Gasoline Fired Engines(^1)</td>
<td>215 hp</td>
<td></td>
</tr>
<tr>
<td>Natural Gas Fired Engines(^2)</td>
<td>80 hp</td>
<td></td>
</tr>
<tr>
<td>Natural Gas Fired Fuel Burning Equipment(^2)</td>
<td>23 MMBtu/hr</td>
<td></td>
</tr>
<tr>
<td>LPG Fired Fuel Burning Equipment(^2)</td>
<td>15 MMBtu/hr</td>
<td></td>
</tr>
<tr>
<td>Diesel Fired Fuel Burning Equipment(^2)</td>
<td>4.5 MMBtu/hr</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) Does not include non-road engines in or on a piece of equipment that
    is self-propelled or engines that serve a dual purpose by both propelling
    itself and performing another function; or is intended to be propelled
    while performing its function (examples: engine powered equipment used
    on utility vehicles, garden tractors, off-highway mobile cranes and
    bulldozers; or engines that can be moved by hand such as lawnmowers,
    string trimmers et. al.).

\(^2\) Does not include sources that are by definition insignificant or
    trivial activities per Title 17 of the PCC.
Attachment 2A
Source Applicability for
Additional ancillary sources (if installed)

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:
   § 3 – Permit Applicability
   § 4 – Permit-Wide Operations
   § 5 – Fossil Fuel Fired Industrial and Commercial Equipment (Boilers and Heaters)
   § 6C – NSPS Requirements for ‘CI’ ICE
   § 8 – Specific Source Applicability

2) Specific Applicability for Item 5 of the equipment list:

   Condition 80: Permitted Facility Sources
   Condition 80.a: Permit-Wide Operations
   Condition 80.b: Fossil-Fuel Fired Industrial and Commercial Equipment (Boilers & Heaters)
   Condition 80.e.iii: New Source Performance Standards for CI ICE
   Condition 81: Local (New and Existing) Stationary Source Performance Standards.
   Condition 82: Exempt Sources.