

gas detection systems which stop the process in safe mode if a leak is detected. Additionally, various maintenance procedures will be implemented including a Leak Detection and Repair program in accordance with EPA guidance.

How are workers at the facility protected from exposure to ethylene oxide?

The site will comply with OSHA's 29 CFR 1910.1047 (Ethylene Oxide Standard) and 29 CFR 1910.119 (Process Safety Management Standard) which regulate all aspects of health and safety to ensure workers are adequately protected against workplace hazards. Main elements of these regulations include:

- *Training*
- *Operating Procedures*
- *Risk assessments*
- *Safe work practices*
- *Personal protective equipment*
- *Maintenance*
- *Industrial hygiene monitoring*
- *Medical Surveillance*
- *Emergency Response*
- *Management of Change*
- *Contractor Management*

The site will have onsite Environmental Health Safety (EHS) professionals to ensure compliance to regulations and to ensure the health and safety of associates. Additionally, the site will be scheduled for routine third party audits by EHS professionals.

How is ethylene oxide stored?

EtO is shipped and stored in DOT approved A1A stainless steel containers. The container valves remain closed with shipping plugs installed to prevent leaks from the containers whilst in storage.

The areas where EtO is stored and used are equipped with gas detection systems and fire protection systems.

Who will govern and monitor storage and plant handling of Ethylene Oxide?

Main regulatory oversight is provided by the following agencies:

- *DOT: transportation and storage of hazardous materials*
- *EPA/PDEQ: environmental compliance (air, waste, water)*
- *OSHA: employee health and safety*
- *FDA: product safety and quality*

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- *CBP: customs and site security*

In addition, the site will work closely with Local Emergency Planning Committees (police, fire, medical) to ensure a robust emergency response plan is implemented.

According to an article in the Star, a BD sterilization facility in Georgia caused a cancer cluster within a 5-mile-radius of the facility, and more than 150 lawsuits were filed against BD in June 2021. What is different about the plant in Tucson than the one in Covington, Georgia? How will a similar situation be avoided?

PDEQ cannot comment on the factual basis of the article in the Arizona Daily Star nor can it comment on facilities outside its jurisdiction. Based on the permit information, however, the Tucson plant will have state-of-the-art air emission controls for both process emissions and fugitive emissions that will result in total emissions that are significantly below health risk standards for issuing an air permit. Additional information from BD indicates:

The facility design has been reviewed by two independent expert organizations (FM and Inotek) to ensure the safety of the facility. A thorough hazard analysis of the process and equipment has been completed using HAZOP methodology. This plant will be fitted with fugitive emissions control systems to capture and control potential fugitive emissions from process equipment and the post sterile warehouse, eliminating the potential for uncontrolled emissions from the site.

Additionally, BD is one of only 12 companies selected by the U.S. Food and Administration (FDA) Innovation Challenge on EtO. BD's activities include: projects that focus on cycle optimization to reduce the amount of EtO used during each sterilization cycle, EtO residual reduction, evaluation of new and emerging alternate sterilization methods and evaluation and implementation of new emission control technologies. BD's implementation of cycle optimization and new control technologies will reduce fugitive emissions by more than 95%.

Is BD investing in researching any alternatives to Ethylene Oxide?

BD and the entire med-tech industry is actively evaluating alternatives to EtO. However, at the moment suitable alternatives have not been proven viable. 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

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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.

PDEQ has included permit elements to ensure the facility complies with all applicable rules, regulations, and ordinances. These include:

- Initial performance testing of the facility within 180 days of startup to determine the efficiency of the control device.
- Yearly performance tests during routine operations. If the efficiency is found to be less than 99%, the facility will restore the Catalyst bed ASAP and no later than 180 days of the decreased efficiency reporting result.
- Yearly analysis of the EtO concentration at the outlet to the atmosphere.
- Ensure the facility replaces the Catalyst bed every 5 years.

Attached is the Air Quality Permit Technical Support Document which provides additional information.

Staff will be available at the December 7 Board of Supervisors Meeting to answer further questions.

Attachment

c: Carmine DeBonis, Jr., Deputy County Administrator for Public Works
Yves Khawam, PhD, Assistant County Administrator for Public Works
Ursula Nelson, Director, Department of Environmental Quality
Diana Durazo, Special Projects Manager, County Administrator's Office

TECHNICAL SUPPORT DOCUMENT (TSD)

SEPTEMBER 2021

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)

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 EP 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 suspected 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 [\angle] that gives the gas molecule a significant molecular angular strain. This atomic strain makes the EO gas molecule unstable and highly reactive. It has the ability to react with many nucleophiles and open the C = C double bond ring of many organic compounds. Through these alkylation, addition, or substitution-type reactions, EO can readily react 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.

Proposed Process and Fugitive EO Emission Controls

The process emissions from the sterilization operations are estimated to be over 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 of at least 99%. These emissions and control systems are regulated by NESHAP Subpart O. As a result these systems will be performance tested on an annual basis to determine their efficiency and emission rate, as well as continuously monitor the catalyst oxidation temperature.

Potential fugitive EO 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 limit these emissions.

Additional Advanced Air Technology[®] dry media bed systems will be installed to control fugitive EO emissions from the following areas at the facility:

- 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. Emissions from the areas will be controlled by 4 independent APC Units.

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 (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.

Ethylene Oxide Emissions Cap

To effectively limit the EO emissions from the facility, the Permittee has accepted a EO emissions cap of 709 lb/yr 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 12-month rolling total basis.

Source Designation	MFG	Description	Amounts Allotted under Cap ¹
APC 1 & 2	LESNI	Process EO – Cat-Ox Abatement System(s) x2	1 PPM _v
APC 3	Advanced Air Technologies	EO from Gas Room Areas	13 lb/yr
APC 4	Advanced Air Technologies	EO from Sterilization Chamber, Aeration & DLC Areas	79 lb/yr
APC 5 – 8	Advanced Air Technologies	EO from WIP and Post Sterilization Areas	527 lb/yr

¹ In accordance with Condition 46.a

The media used in the dry beds is designed to react with the EO and the EO is reduced 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 chemisorbed and treated in the dry beds is proportional to the amount of reactant at the APC systems. From the manufacturer's information, the sum total of dry media contained in the units is approximately 21,600 lbs of dry chemi-sorbant media, which is estimated to have a capacity to control approximately 6,000 lb of EO at an efficiency of around 99%. It is estimated that the dry bed media will need replacement approximately every two years.

The permit provides enforceable limits on both the fugitive APC discharge vent concentrations and the total EO emissions from the facility as a 12 month rolling total and sets out procedures to monitor the emissions from the APC systems through quarterly performance testing of the discharge streams. The actual emissions from each APC system will be monitored and quantified periodically and used to estimate the emissions for the previous quarter and the monthly totals in the permit emission cap.

The facility has been designed around an annual EO usage of about 225 tons of EO/yr. The permit caps the EO emissions from the facility to 709 lb/yr based on a 12-month rolling total. The cap will be monitored and demonstrated by determining the emission rates from the fugitive EO APC (3 – 8) monitored each quarter and APC 1 & 2 monitored at least annually. Compliance with the emission cap will ensure the facility emissions are controlled to less than the amounts modeled which accompanies the permit application. It is worth noting that the actual emission rates from the facility averaged over a long term period (> 2 years) will be almost half of the allowed permit limits, if the media is consistently exchanged in two year cycles, since the discharge concentration only approaches the allowed permit limits near the end dry bed sorbent media life cycle. The life of the sorbent media is proportional to the EO usage of the facility and EO usage may be used to track the remaining life of the media.

BD has submitted a model of the pollution impact from the facility prepared by Trinity Consultants, LLC that demonstrates that the allowable emissions are adequately protective of the health of the public residing near the facility in accordance with the EPA's IRIS database latest findings. As stated above, the emission levels from the facility are expected to be lower when averaged over longer time frames. Furthermore, the maximum allowable EO discharge concentrations of 100 and 200 micrograms/cubic meter from the discharge vents is equivalent to between 1/20th and 1/10th of the current limit of 1 PPM in Subpart O, and OSHA's time weighted average 8-hour permissible exposure level (8-hr TWA – PEL).

Within the last few years, EPA's air toxics program in coordination with state and local agencies has gathered 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 study EO sources and impacts from such sources on public health.

C. Attainment Classification

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

II. SOURCE DESCRIPTION

A. Process Description

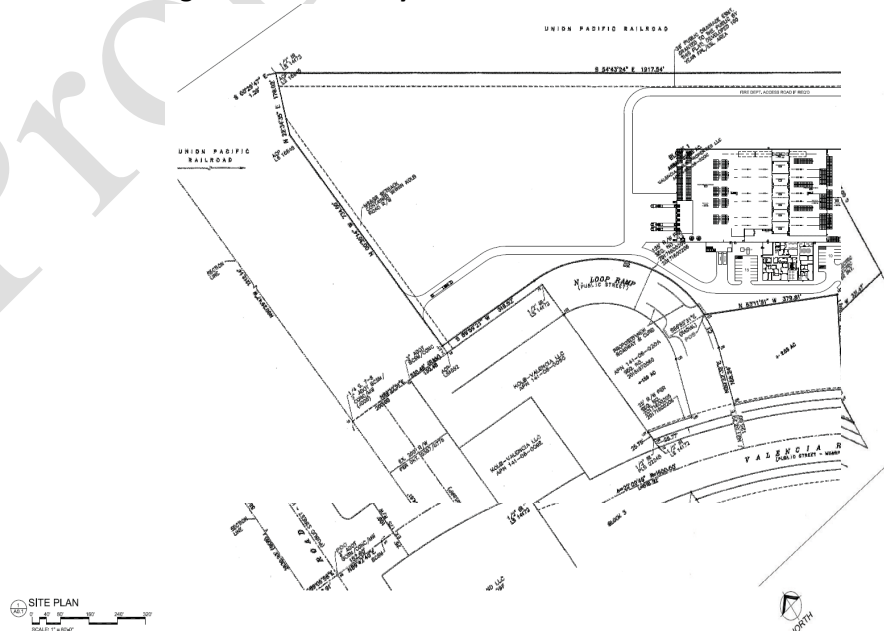
1. Overview of Ethylene Oxide Sterilization Facility

BD is proposing to construct and operate an EO sterilization facility in Tucson on a 32.7-acre parcel (Block 1) in Century Park Marketplace. Figure 1 shows the location of the proposed facility.

Figure 1. Site Location



Figure 2. Preliminary Site Plan as shown in Block 1 above



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.
- 2) **Sterilization:** In this step, the product is exposed to EO inside a sterilization chamber under controlled conditions.
- 3) **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.

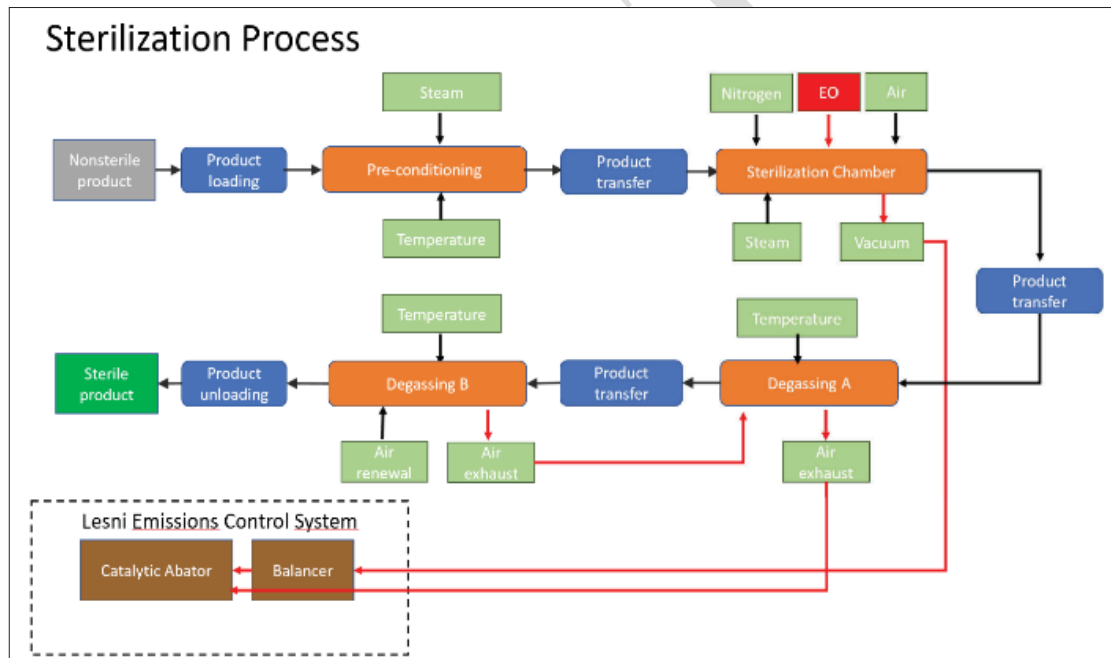
b. Step 2: Sterilization

- 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



4. Emission Controls

As described in the steps detailed in Sections I.D.3.a through c, 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 ($\mu\text{g}/\text{m}^3$). 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 proposes to 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 IIII, 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.

Source Type and Category	<u>Conventional or Criteria</u> Air Pollutants								NSPS or NESHAP Pollutant	<u>HAP(s)</u>		CO ₂ e
	PM _{2.5}	PM ₁₀	PM	NO _x	VOC	CO	SO ₂	Pb	EO	Total	Single	
Sterilization ¹	-	-	-	-	0.36	-	-	Neg.	0.36	0.36	0.36	-
Boilers	0.82	0.82	0.82	1.17	0.59	3.97	0.06	Neg.	-	0.20	< 0.2	4190
Fire Pump	0.00	0.00	0.00	0.01	0.00	0.07	0.03	Neg.	-	-	-	5.7
Generator	0.00	0.00	0.00	0.03	0.01	0.28	0.00	Neg.	-	0.00	0.00	20.4
Total Estimated Emissions	0.82	0.82	0.82	1.21	0.96	4.33	0.09	Neg.	-	< 0.56	< 0.56	4214

¹ The estimates of point source emissions only from LESNI and Advanced Air Technology air pollution control devices. See Figure 4 and Table 2 below for details on emissions points and emission estimates.

Table 2: Estimated Ethylene Oxide Sterilization Emissions

Estimated Ethylene Oxide Use (lb/yr)	450,000
Percent of Use as Process Emissions ^a	99.5
Lesni Catalytic Oxidizer Control Efficiency (Percent) ^b	99.98
Process Ethylene Oxide Emissions (lb/yr)	89.55
Gas Room Ethylene Oxide Discharge Concentration (ug/m ³)	100
Gas Room Ethylene Oxide Discharge Concentration (ppm)	0.06
Exhaust Air Flow (cfm)	4,000
Exhaust Air Flow (scfm)	3,950
Gas Room Ethylene Oxide Emissions (lb/hr)	0.002
Gas Room Ethylene Oxide Emissions (lb/yr)	13
DLC Ethylene Oxide Discharge Concentration (ug/m ³)	100
DLC Ethylene Oxide Discharge Concentration (ppm)	0.06
Exhaust Air Flow (cfm)	24,000
Exhaust Air Flow (scfm)	23,701
DLC Ethylene Oxide Emissions (lb/hr)	0.009
DLC Ethylene Oxide Emissions (lb/yr)	79
WIP Area Ethylene Oxide Discharge Concentration (ug/m ³)	200
WIP Area Ethylene Oxide Discharge Concentration (ppm)	0.11
Exhaust Air Flow (cfm)	80,000
Exhaust Air Flow (scfm)	79,002
WIP Area Ethylene Oxide Emissions (lb/hr)	0.060
WIP Area Ethylene Oxide Emissions (lb/yr)	527
Total Ethylene Oxide Emissions (lb/yr)	709
Total Ethylene Oxide Emissions (tpy)	0.35

^a 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.

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

^c 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) x (discharge flow rate in scfm) x (44.05 lb/mol) x (mol/385.32 scf) x 1/10⁶
x60 min/hr359 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. At the time of this writing BD is in full compliance with EPA regulations and any outstanding consent orders for their facilities operating in the in the United States, and 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 IIII for the stationary compression ignition ICE source category in 40 CFR Part 60, NSPS. 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 IIII NSPS for Compression Ignition Internal Combustion Engines
- Appendix A Test Methods.

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

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

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

- Article I – General Provisions*
 - 17.11.010 Statutory Authority.
 - 17.11.020 Planning, Constructing, or Operating Without a Permit.
- Article II – General Provisions for Stationary Source Permits*
 - 17.11.060 Permit Display or Posting.
 - 17.11.070 Public records – Confidentiality.
 - 17.11.090 Applicability – Classes of permits.
 - 17.11.100 Permits for State Delegated Emission Sources.
 - 17.11.110 Portable Sources.
 - 17.11.120 Material permit condition.
 - 17.11.150 Stack height limitation.
 - 17.11.160 Test methods and procedures.
 - 17.11.190 Permits containing synthetic emission limitations and standards.
 - 17.11.210 Performance tests.

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

- Article I – General Provisions*
 - 17.13.010 Application processing procedures.
 - 17.13.020 Permit contents.
- Article II – Permit Revisions, Renewals and Transfers for Class II and III Permits*
 - 17.13.100 Facility changes that require a permit revision.
 - 17.13.110 Procedures for certain changes that do not require a permit revision.
 - 17.13.120 Administrative amendments for Class II and Class III permits.
 - 17.13.130 Minor revisions.
 - 17.13.140 Significant revisions.
 - 17.13.150 Reopening, revocation, or termination.
- Article III – Emissions for Class II and Class III Sources*
 - 17.13.180 Annual Emissions inventory questionnaire.
 - 17.13.190 Excess emissions reporting requirements.

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

Article V – Fees for Class II and Class III Sources

17.13.230 General Provisions.

17.13.240 Fees related to Class II and Class III permits.

Pima County Code Title 17, Chapter 17.14 – Activity Permits

Article I – General Provisions

17.16.040 Fugitive dust activity permits

17.14.060 Asbestos NESHAP activity permits.

17.14.080 Open burning permits.

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

Article I – General Provisions

17.16.010 Local rules and standards; Applicability of more than one standard.

17.16.020 Noncompliance with applicable standards.

17.16.030 Odor limiting standards.

Article II – Visible Emission Standards

17.16.040 Standards and applicability (includes NESHAP).

17.16.050 Visibility limiting standard.

Article III – Emissions from Existing and Nonpoint Sources(inclusive)

Article IV – New and Existing Stationary Source Performance Standards

17.16.130 Applicability

17.16.165 Standards of performance for fossil-fuel fired industrial and commercial equipment

17.16.430 Standards of performance for unclassified sources

17.16.490.A.1 NSPS – Subpart A – General Provisions

17.16.530.B.1 NESHAP – Subpart A – General Provisions

17.16.530.B.12 NESHAP – Subpart O – EO Emission Standards for Sterilization Facilities

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

Article I – General Provisions

17.20.010 Source sampling, monitoring and testing

Article II – Concealment of Emissions

17.20.040 Concealment of emissions

Article III – Compliance Inspections

17.20.050 Compliance Inspections

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

Article I – Availability of Information

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

Article II – Recordkeeping Requirements

17.24.020 Recordkeeping for compliance determination

Article III – Reporting Requirements

17.24.050 Reporting as a permit requirement

17.24.060 Reporting for emission inventories

Article IV – Penalty for noncompliance (inclusive)

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

Article I – Violations (inclusive)

Article II – Conditional Orders (inclusive)

Article III – Circumvention (inclusive)

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 20).

C. § 2: Definitions

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

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

D. § 3: Permit Applicability

§ 3 contains the general permit applicability, classification, and outline of the permitted sources and applicable 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 of 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 as demonstrated by emissions estimates and modeling submitted with the application on file with the Control Officer. This provision provides a means for the Administrator, Control Officer, or citizens to challenge or require the permit to be reopened, or revised should there be changes to the basic design of the facility, future expansions, modification, revision to the current EPA policies or NESHAP Subpart O provisions, or findings with respect to the modeling that demonstrates compliance.

E. § 4: Emission Limitations and Standards:

Local and State Requirements

- 40-42 Permit wide limits, general control requirements, operation and maintenance requirements,
- 43 Opacity
- 44 Visibility

NESHAP Subpart O (In Attachment 4 of the Permit)

- 45 Applicability
Except as provided in Condition 33 of the permit, wherever the terms and Conditions in 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.

- 45a 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 17.11.190 & 17.13.070

46 Applicability

As of the date of issuance of the permit, the emission limits in this section are demonstrated to be adequate to protect the public health and welfare 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. Should any conditions at the facility, Conditions in this permit, change this determination, the Permittee shall report such a finding and submit a revision to this permit in accordance with Conditions 6.b and 14.

46.a EO Emission Cap

46.a.i Limit not to exceed: 709 lb of EO monitored as a 12-month rolling total

46.b Operation Requirements of APC 3 – 8,

46.b.i O & M Plan for APC 3 – 8

46.b.i.(a) To include daily pressure drop, periodic visual inspection, proposed testing strategy, maintenance of the system(s).

46.b.i.(b) Tracking of PT results, emission rates, and APC performance, remaining media capacity.

46.b.i.(c) For each APC, inspection forms and records to document, pressure drop, amount of EO used, hours of operation, hours removed for maintenance, corrective actions, deviations or malfunctions, and their duration.

46.b.i.(d) Periodic measurements and parameters to be monitored by the Building Management System to include: all doors and openings closed except when in use. Operational status of APC, Negative pressure indicators, and malfunction.

46.b.i.(d) Parameters to monitor collection and building Management System

46 Table 2 – APC Emission Limits; Operating Limits; and Test Schedule

Ancillary Operations

47 Ancillary Operations (See Attachment 5 & 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 for maintenance of records for operating limits and parameters when specified in the equipment list and quarterly and 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. Contains references to monitoring requirements in the General Provisions, and Attachment 6 (GP attachments) for summary of monitoring, recordkeeping and reporting requirements in the Permit.

52. NESHAP Subpart O (in Attachment 4 of the Permit)

52. Applicability 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 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. Fugitive EO Emission Controls pursuant to 17.11.190 & 17.13.070

- 53.a EO Emissions Cap
- 53a.i APC units 1 and 2 – Process EO Emissions
Determination of emission rates, in lb/month (lb/yr / 12)
- 53a.ii APC units 3 – 8 Fugitive EO emissions
Determination of emission rates according to schedule in Table 1 of Condition 46
Determination of discharge vent flow rates
Allowance to revise O & M Plan following first two years after startup and determination of consistent and reliable APC performance. Options to reduce number of PT and monitoring.
Emission documented in spreadsheet to demonstrate compliance with cap in Condition 46.a.i
Each day the calculated emission rate exceeds the cap in Condition 46.a.i is considered an exceedance.
- 53.b Recordkeeping requirements

§ 5b Testing Provisions

54. NESHAP Subpart O

- 54.a-e Performance Testing Provisions including EPA 320 and ALT 142

55. Fugitive EO Emission Controls pursuant to 17.11.190 & 17.13.070

- 55.a TO-15A – SIM
- 55.b Sampling Methodology
- 55.c Air flow parameter measurements
- 55.d Outlet Concentrations verified to meet permit limits
- 55.e Series of PT using reference Method 320 vs TO-15A-SIM to verify within 10%.
- 55.f If mutually agreed, once a protocol has been approved no longer necessary prior to each PT.
- 55.g Waiver to submit full written test reports if mutually agreed and satisfied with test procedures and methodology.

§ 5c Reporting Provisions

56. Permit-Wide Provisions

- Aligned Permit Reporting Dates (as applicable)
- 56.a Periodic Reports
- 56.a.i Annual Summary Reports of Required Monitoring
 - (a) Emission Cap Spreadsheet with monthly rates and 12-month rolling total
 - (b) Most Recent performance test report and emission discharge rate of LESNI cat-ox APC 1 & 2
 - (c) Performance Summary Reports for APC 3 – 8 including duration of deviations and malfunctions.
 - (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
 - i. The O & M plan in accordance with Condition 46.b.i
 - ii. NESHAP Subpart O notifications and reports
 - iii. Reports and notifications in Condition 9.

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 are submittals 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

VII. PERIODIC MONITORING

The permit requires periodic monitoring in accordance with an approved O & M plan to include annual performance testing of the LESNI cat-ox EO abatement systems, and quarterly testing of APC 3 – 8 for the first two years. If results are shown to be reliable and consistent. The testing for APC 3 – 8 may be reduced in accordance with an approved O & M plan. The control officer may revert to quarterly testing if there is an exceedance or if the test results are not consistent or reliable.

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.

IX. CONTROL TECHNOLOGY DETERMINATION

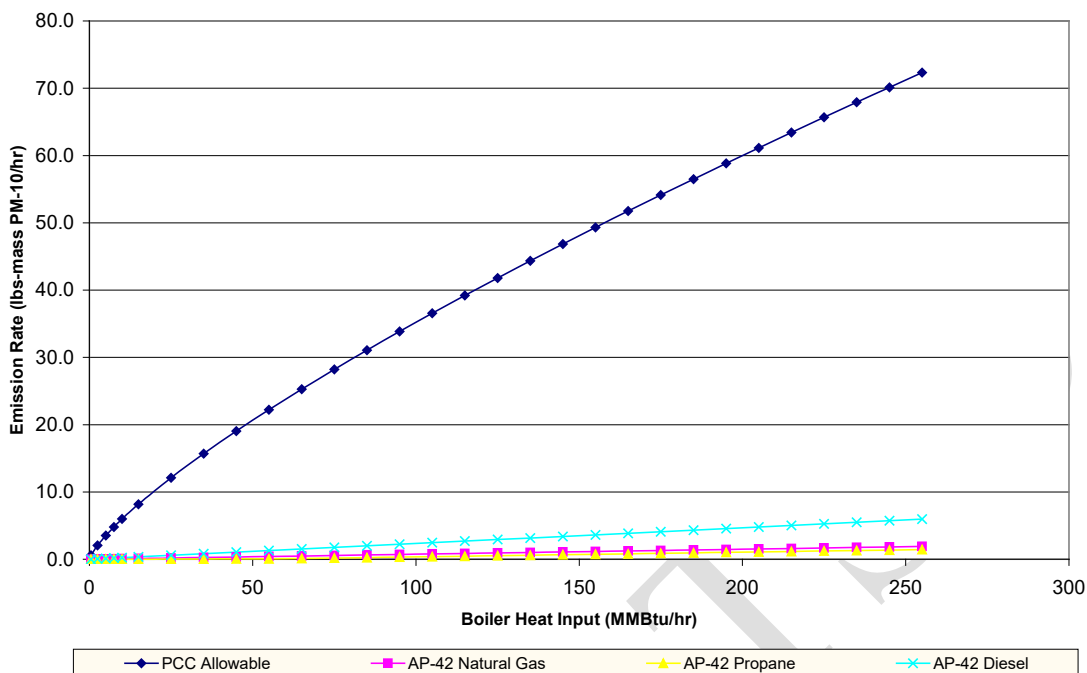
No control technologies have been required by Title 17 of the PCC and the source has not been subject to RACT, BACT or LAER. Additional fugitive EO controls have been accepted by BD and as provided in the permit demonstrating safe ambient air concentration levels will be maintained in accordance with EPA risk factors in the IRIS database and in anticipation of any future NESHAP subpart O rule making.

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



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)

	APC 1	APC 2
HAP & VOC (EO):	0.005 lb/hr	0.005 lb/hr

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

	APC 3	APC 4	APC 5	APC 6	APC 7	APC 8
HAP & VOC (EO):	0.0014 lb/hr	0.009 lb/hr	0.015 lb/hr	0.015 lb/hr	0.015 lb/hr	0.015 lb/hr

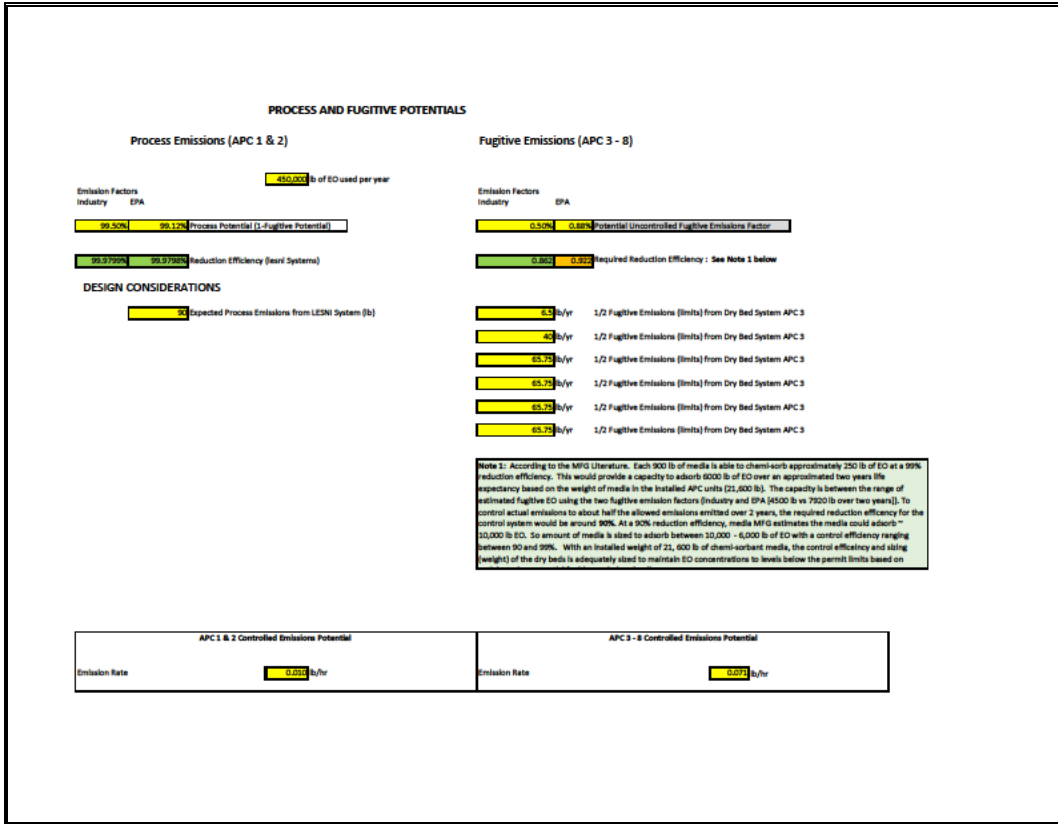
3. Boilers and Generators

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)

Source	PM₁₀	PM_{2.5}	CO	NO_x	SO₂	VOCs	HAPs
Sterilization Operations (EO)	-	-	-	-	-	0.36	0.36
Boilers and Generators	0.82	0.82	4.33	1.21	0.09	0.60	0.20
Total	0.82	0.82	4.33	1.21	0.09	0.96	0.56

Double Click Image Below to See in PDF format.



ATTACHMENT 2: SOURCE APPLICABILITY

(Unless otherwise noted, references are to [Title 17](#) of the Pima County Code (PCC), Arizona Revised Statutes (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)

[PCC 17.16.010., PCC 17.16.020 thru 050, PCC 17.16.230.D, PCC 17.16.400.A, & PCC 17.16.430.F]

- 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 this Condition 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 Conditions in the permit, change such a determination, the permit will be reopened to address such findings.

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 the APC units 3 – 8 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 action taken to restore units or parameters to their proper function.

As required by the O & M plan, the Permittee shall demonstrate compliance with the plan criteria to establish monitoring of parameters for the APC units 3 – 8 including the building monitoring system.

d. Additional Ancillary Sources and Operations **[Federally and Locally Enforceable Conditions]**

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. [17.04.340.A (114.j & 129), PCC 17.13.110.C.2]
- 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. [PCC17.16.010]
- iii. The owner or operator of any portable source which incinerates any material shall keep complete records of all materials incinerated. [PCC 17.16.010]

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 1: Insignificant Activities

Description	Maximum Rated Capacity	Fuels Used or Materials Affected
1) Landscaping, building maintenance, or janitorial services.		
2) The following Gasoline and Volatile Organic liquid (VOL) Storage Tanks: - All gasoline storage tanks less than 250 gallons capacity provided they otherwise comply with <u>40 CFR 59, Subpart F.</u> , - Gasoline storage tanks greater than 250 gallons and less than 10,000 gallons with a throughput less than 1000 gallons per month, provided such tanks are equipped with a submerged filling device, or acceptable equivalent, for the control of hydrocarbon emissions in accordance with <u>PCC 17.16.230.B</u> - Gasoline storage tanks less than 10,000 gallons capacity provided they are not otherwise required to meet <u>NESHAP Subpart 6C.</u> - All volatile organic liquid (VOL) tanks less than 10,000 gallons provided they comply with Condition 38.a of the permit.	V ≤ 10,000 gal.	Gasoline or VOL
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.	Petroleum liquid or VOL	
Cutoff for monitoring per PCC 17.16.230.E.2 and/or NSPS Subpart Kb:		
a) Petroleum Liquids with a max. true vapor pressure < 0.50 psia (3.5 kPa) under actual storage conditions.	All sizes	Petroleum liquid
b) VOL with a max true vapor pressure < 2.17 psia (15 kPa) under actual storage conditions	V > 10K gal. V < 40K gal.	VOL
c) VOL with a max true vapor pressures < 0.5 psia (3.5 kPa) under actual storage conditions	V > 40K gal.	VOL
4) Diesel, Fuel Oil, or Jet A storage tanks	All sizes	
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 art work, 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)

Description	Maximum Rated Capacity	Fuels Used																		
<p>9) Internal combustion (IC) engine-driven compressors, IC engine-driven electrical generator sets and IC engine-driven water pumps used only for emergency replacement or standby service.</p> <p>Note: Portable or temporary internal combustion engines (ICE) or non-road engines that operate, or are planned for operation, at a fixed location for more than 12 months shall be subject to stationary source permitting requirements. Portable ICE used or located at a facility, may be required to keep records as provided in Condition 2.b of this Attachment to document when the ICE is transferred to or from the facility, or alternate locations at the facility, and/or storage areas in order to establish that the unit is not subject to stationary permitting requirements.</p> <p>Portable ICE that are used to replace a stationary ICE at a fixed location and intended to perform the same or similar function shall include the time period of both engines to determine the consecutive time period for purposes of stationary ICE permitting.</p> <p>Notwithstanding the stationary ICE permitting requirement, a portable ICE shall not be required to meet the NSPS or NESHAP ICE standards for stationary sources when used as an emergency replacement or as a standby unit, while the facility effects repairs, or while ordering a replacement unit, unless the Permittee intends for the replacement portable ICE to be permanent.</p> <p>Portable ICE used to replace a stationary permitted ICE shall be limited by the same run hour limits (if any) applicable to the replaced unit at that facility location. The balance of the permitted allowable run hours allotted to the stationary ICE shall continue to accrue with the operation of the replacement unit. When used for this specific purpose, the permittee shall be required to keep records of the run hours and emissions of the portable ICE for emission inventory purposes.</p>																				
<p>10) Lab equipment used exclusively for chemical and physical analyses.</p>																				
<p>11) Trivial activities as provided in PCC 17.04.340.a.237 a through xx.</p>																				
<p>12) The Control Officer has deemed the following portable sources located at a facility and having a combined capacity less than the amount in its FBE class, as listed below, to be an insignificant activity per Condition 2.b of this attachment, and not requiring documentation to demonstrate their portable source status:</p> <p style="text-align: center;"><u>Fuel Burning Equipment (FBE) Class</u></p> <table border="1" data-bbox="511 1115 1380 1350"> <tbody> <tr> <td data-bbox="511 1115 1003 1157">Diesel Fired Engines ¹</td> <td data-bbox="1003 1115 1203 1157">75 hp</td> <td data-bbox="1203 1115 1380 1157"></td> </tr> <tr> <td data-bbox="511 1157 1003 1199">Gasoline Fired Engines ¹</td> <td data-bbox="1003 1157 1203 1199">215 hp</td> <td data-bbox="1203 1157 1380 1199"></td> </tr> <tr> <td data-bbox="511 1199 1003 1241">Natural Gas Fired Engines ²</td> <td data-bbox="1003 1199 1203 1241">80 hp</td> <td data-bbox="1203 1199 1380 1241"></td> </tr> <tr> <td data-bbox="511 1241 1003 1283">Natural Gas Fired Fuel Burning Equipment ²</td> <td data-bbox="1003 1241 1203 1283">23 MMBtu/hr</td> <td data-bbox="1203 1241 1380 1283"></td> </tr> <tr> <td data-bbox="511 1283 1003 1325">LPG Fired Fuel Burning Equipment ²</td> <td data-bbox="1003 1283 1203 1325">15 MMBtu/hr</td> <td data-bbox="1203 1283 1380 1325"></td> </tr> <tr> <td data-bbox="511 1325 1003 1350">Diesel Fired Fuel Burning Equipment ²</td> <td data-bbox="1003 1325 1203 1350">4.5 MMBtu/hr</td> <td data-bbox="1203 1325 1380 1350"></td> </tr> </tbody> </table> <p>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.).</p> <p>² Does not include sources that are by definition insignificant or trivial activities per Title 17 of the PCC.</p>	Diesel Fired Engines ¹	75 hp		Gasoline Fired Engines ¹	215 hp		Natural Gas Fired Engines ²	80 hp		Natural Gas Fired Fuel Burning Equipment ²	23 MMBtu/hr		LPG Fired Fuel Burning Equipment ²	15 MMBtu/hr		Diesel Fired Fuel Burning Equipment ²	4.5 MMBtu/hr			
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LPG Fired Fuel Burning Equipment ²	15 MMBtu/hr																			
Diesel Fired Fuel Burning Equipment ²	4.5 MMBtu/hr																			

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:

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 3
O & M Plan or other Forms that may be used with the permit