Florida Department of Environmental Protection

Southwest District Office
13051 North Telecom Parkway
Temple Terrace, Florida 33637-0926

Rick Scott
Governor

Jennifer Carroll
Lt. Governor

Herschel T. Vinyard Jr.
Secretary

FINAL PERMIT

PERMITTEE

Synergy Health AST, LLC
401 Commerce Blvd.
Oldsmar, FL 34677

Authorized Representative:
Mr. Ray Aaron, Operations Manager

Air Permit No. 1030197-016-AC
Permit Expires: 07/30/2013
Site Name : Oldsmar Florida Facility
Minor Air Construction Permit
Construction Modification

This is the final air construction permit for the construction of (4) new ethylene oxide sterilization chambers (already authorized by Construction Permit 1030197-015-AC), a dry bed scrubber, an aeration room and an up to 5,000 gallon auxiliary storage tank for the existing wet scrubber. The proposed work will be conducted at the Oldsmar Florida Facility (Standard Industrial Classification No. 5047). The facility is located in Pinellas County at 401 Commerce Boulevard in Oldsmar, Florida. The UTM coordinates are Zone 17, 336.71 km East, and 3103.19 km North. As noted in the Final Determination provided with this final permit, no changes or only minor changes and clarifications were made to the final permit.

This final permit is organized by the following sections:

Section 1. General Information

Section 2. Administrative Requirements and Facility-wide Specific Conditions

Section 3. Emissions Unit Specific Conditions

Section 4. Appendices

Due to the technical nature of the project, the permit contains numerous acronyms and abbreviations, which are defined in Appendix A of Section 4 of this permit.

This air pollution permit is issued under the provisions of: Chapter 403 of the Florida Statutes (F.S.) and Chapters 62-4, 62-204, 62-210, 62-212, 62-296 and 62-297 of the Florida Administrative Code (F.A.C.). The permittee is authorized to conduct the proposed work in accordance with the conditions of this permit. This project is subject to the general preconstruction review requirements in Rule 62-212.300, F.A.C. and is not subject to the preconstruction review requirements for major stationary sources in Rule 62-212.400, F.A.C. for the Prevention of Significant Deterioration (PSD) of Air Quality.

Upon issuance of this final permit, any party to this order has the right to seek judicial review of it under Section 120.68 of the Florida Statutes by filing a notice of appeal under Rule 9.110 of the Florida Rules of Appellate Procedure with the clerk of the Department of Environmental Protection in the Office of General Counsel (Mail Station #35, 3900 Commonwealth Boulevard, Tallahassee, Florida, 32399-3000) and by filing a copy of the notice of appeal accompanied by

the applicable filing fees with the appropriate District Court of Appeal. The notice must be filed within 30 days after this order is filed with the clerk of the Department.

Executed in Hillsborough County, Florida

_____ _____

Robert C. Wong Effective Date
District Air Program Administrator
Southwest District

CERTIFICATE OF SERVICE

The undersigned duly designated deputy agency clerk hereby certifies that this Final Air Permit package (including the Final Determination, the Final Permit and the Appendices) was sent by electronic mail (or a link to these documents made available electronically on a publicly accessible server) with received receipt requested before the close of business on _____ to the persons listed below.

Ray Aaron, Synergy Health AST, LLC (raaron@beam-one.com)
Tony Valentyn, Synergy Health AST, LLC (tvalentyn@beam-one.com)
Robert A. Baker, Baker Environmental Engineering, Inc. (baker@atlantic.net)
Gary Robbins, PCAQD (grobbins@pinellascounty.org)

Clerk Stamp

FILING AND ACKNOWLEDGMENT FILED, on this date, pursuant to Section 120.52(7), Florida Statutes, with the designated agency clerk, receipt of which is hereby acknowledged.

_____ _____

(Clerk) (Date)

FACILITY AND PROJECT DESCRIPTION

Existing Facility

This facility consists of the operation of an ethylene oxide sterilization chamber that is used to sterilize custom surgical pallets for the health care industry as well as other medical supplies. The existing facility consists of the following emissions units.

Facility ID No. 1030197	
ID No.	Emission Unit Description
001	Ethylene Oxide Sterilization Unit

Project Description and Affected Emission Unit

This project is for the construction of a dry bed scrubber, aeration room #4 and an up to 5,000 gallon auxiliary storage tank for the existing wet scrubber. This project revises Construction Permit 1030197-015-AC for the construction of four (4) additional sterilization chambers (increasing the emission unit from one (1) sterilization chamber to five (5) sterilization chambers). This project also modifies compliance testing requirements. The allowable emissions did not change in this permit.

This project will modify the following emissions units.

Facility ID No. 1030197	
ID No.	Emission Unit Description
001	Ethylene Oxide Sterilization Units

NOTE: *Please reference the Permit No., Facility ID, and Emission Unit ID in all correspondence, test report submittals, applications, etc.*

Exempt Emission Units/Activities

- 2.1 MM Btu/hr Natural Gas Boiler [Rule 62-210.300(3)(a)(33), F.A.C.]
- 375 HP Emergency Generator – Diesel Fired [Rule 62-210.300(3)(a)35(d), F.A.C.]
- 244 HP Fire Pump Engine – Diesel Fired [Rule 62-210.300(3)(a)35(d), F.A.C.]
- Ethylene Oxide Tanks [Rule 62-210.300(3)(b)1, F.A.C.]
- Paved roadways, parking lots, truck loading and unloading operations [Rule 62-210.300(3)(b)1, F.A.C.]
- Chemical/solvent/waste storage drums [Rule 62-210.300(3)(b)1, F.A.C.]
- Fugitives from minor spills or leaks [Rule 62-210.300(3)(b)1, F.A.C.]
- Tank degassing and cleaning [Rule 62-210.300(3)(b)1, F.A.C.]

FACILITY REGULATORY CLASSIFICATION

- The facility is not a major source of hazardous air pollutants (HAP).
- The facility has no units subject to the acid rain provisions of the Clean Air Act (CAA).
- The facility is not a Title V major source of air pollution in accordance with Chapter 62-213, F.A.C.

- The facility is not a major stationary source in accordance with Rule 62-212.400(PSD), F.A.C.
- This facility is a synthetic non-Title V source for HAPs (Hazardous Air Pollutants).
- A 375 HP Diesel Fired Emergency Generator. If the engine is or becomes subject to 40 CFR 60, Subpart IIII, Standards for Performance for Stationary Compression Ignition Internal Combustion Engines, 40 CFR 60, Subpart JJJJ, Standards of Performance for Stationary Spark Ignition Internal Combustion Engines or 40 CFR 63, Subpart ZZZZ, National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines, the affected engine(s) shall comply with all limitations and requirements of that subpart.
- The ethylene oxide sterilization process is regulated under National Emissions Standards for Hazards Air Pollutants (NESHAP) – 40 CFR 63, Subpart O – Ethylene Oxide Emission Standards for Sterilization Plants and the general provisions of 40 CFR 63, Subpart A - General Standards, where applicable.

PERMIT HISTORY/AFFECTED PERMITS

Revises and replaces Construction Permit No.1030197-015-AC

SECTION 2. ADMINISTRATIVE REQUIREMENTS AND FACILITY-WIDE SPECIFIC CONDITIONS (FINAL)

1. Permitting Authority: The permitting authority for this project is the Florida Department of Environmental Protection (Department), Southwest District's Air Resource Management Section. The Southwest District's mailing address and phone number is:

   Florida Department of Environmental Protection
   Southwest District Office
   Air Resource Management Section
   13051 North Telecom Parkway
   Temple Terrace, Florida 33637-0926
   Telephone: 813-632-7600

   All documents related to applications for permits shall be submitted to the above address.

2. Compliance Authority: All documents related to compliance activities such as reports, tests, and notifications shall be submitted to the Pinellas County Air Quality Division (PCAQD).

   Pinellas County Air Quality Division
   300 South Garden Avenue
   Clearwater, Florida 33756
   Telephone: 727-464-4422

3. Appendices: The following Appendices are attached as part of this permit:
   a. Appendix A. Citation Formats and Glossary of Common Terms;
   b. Appendix B. General Conditions;
   c. Appendix C. Common Conditions; and
   d. Appendix D. Common Testing Requirements.
   e. Appendix E. Applicability Table for 40 CFR 63 Subpart O - Ethylene Oxide Emissions Standards for Sterilization Facilities
   f. Appendix F. Applicability Table for 40 CFR 63 Subpart A – General Provisions
   g. Appendix G. Figure 1 Synergy Health AST, LLC – Facility Plot Plan

4. Applicable Regulations, Forms and Application Procedures: Unless otherwise specified in this permit, the construction and operation of the subject emissions units shall be in accordance with the capacities and specifications stated in the application. The facility is subject to all applicable provisions of: Chapter 403, F.S.; and Chapters 62-4, 62-204, 62-210, 62-212, 62-213, 62-296 and 62-297, F.A.C. Issuance of this permit does not relieve the permittee from compliance with any applicable federal, state, or local permitting or regulations.

5. New or Additional Conditions: For good cause shown and after notice and an administrative hearing, if requested, the Department may require the permittee to conform to new or additional conditions. The Department shall allow the permittee a reasonable time to conform to the new or additional conditions, and on application of the permittee, the Department may grant additional time.
   [Rule 62-4.080, F.A.C.]

6. Modifications: Unless otherwise exempt by rule, the permittee shall not initiate any construction, reconstruction, or modification at the facility and shall not install/modify any pollution control

device at the facility without obtaining prior authorization from the Department. Modification is defined as: Any physical change or changes in the method of operations or addition to a facility that would result in an increase in the actual emissions of any air pollutant subject to air regulations, including any not previously emitted, from any emission unit or facility.
[Rules 62-210.200 - Definition of "Modification" and 62-210.300(1)(a), F.A.C.]

7. General Pollutant Emission Limiting Standards: Objectionable Odor Prohibited - No person shall cause, suffer, allow, or permit the discharge of air pollutants which cause or contribute to an objectionable odor. Objectionable odor is defined as any odor present in the outdoor atmosphere which by itself or in combination with other odors, is or may be harmful or injurious to human health or welfare, which unreasonably interferes with the comfortable use and enjoyment of life or property, or which creates a nuisance.
[Rules 62-210.200 ("Objectionable Odor") and 62-296.320(2), F.A.C.; Pinellas County Code, Section 58-178]

8. General Pollutant Emission Limiting Standards: Volatile Organic Compounds (VOC) Emissions or Organic Solvents (OS) Emissions - The permittee shall allow no person to store, pump, handle, process, load, unload or use in any process or installation, volatile organic compounds (VOC) or organic solvents (OS) without applying known and existing vapor emission control devices or systems deemed necessary and ordered by the Department. All equipment, pipes, hoses, lids, fittings, etc. shall be operated/ maintained in such a manner as to minimize leaks and fugitive emissions of ethylene oxide.
[Rule 62-296.320(1)(a), F.A.C.]

9. Annual Operating Report: On or before **April 1** of each year, the permittee shall submit a completed DEP Form 62-210.900(5), "Annual Operating Report for Air Pollutant Emitting Facility" (AOR) for the preceding calendar year. The report may be submitted electronically in accordance with the instructions received with the AOR package sent by the Department, or a hardcopy may be sent to the Compliance Authority.
[Rule 62-210.370(3), F.A.C.]

10. Application for Air Operation Permit: This permit authorizes modification of the permitted emissions unit(s) and initial operation to determine compliance with Department rules. An air operation permit is required for continued operation of the permitted emissions unit(s). The permittee shall apply for an air operation permit at least 90 days prior to expiration of this permit, but no later than 180 days after commencing operation of each of the new sterilization chambers. Commencing operation means setting into operation of any emissions unit for any purpose. To apply for an air operation permit, the applicant shall submit the following:

    a. the appropriate permit application form *(see current version of Rule 62-210.900, F.A.C. (Forms and Instructions), and/or FDEP Division of Air Resource Management website at: http://www.dep.state.fl.us/air/)*;

    b. the appropriate operation permit application fee from Rule 62-4.050(4)(a), F.A.C.; and

    c. a copy of the initial compliance test report(s) required by Specific Condition No. A.15., if not previously submitted; and

d. copies of the most recent two months of records/logs specified in Specific Condition No. A.16.; and

e. A copy of the proposed O & M plan for the dry scrubber to include a detailed monitoring plan.

The application shall be submitted to the Permitting Authority with a copy to PCAQD.
[Rules 62-4.030, 62-4.050, 62-4.220 and Chapter 62-213, F.A.C.]

A. EU No. 001 Ethylene Oxide Sterilization Units

This section of the permit addresses the following emissions unit.

ID No.	Emission Unit Description
001	Ethylene Oxide Sterilization Process Synergy Health has several steps in the sterilization process: • Items to be sterilized are reconditioned at specific temperatures and humidity levels. • Items are placed on pallets and sterilized in a sterilization chamber by the use of Ethylene Oxide (EtO) gas. • The sterilized items are placed in aeration rooms which are maintained at a specific temperature to allow the items to degas. • Sterilized items are stored in the general warehouse to await shipment. <u>Preconditioning</u> Incoming items to be sterilized are loaded onto pallets. Some of the pallets are wrapped in plastic. The preconditioning room is controlled for desired temperature and humidity conditions. This is done to maximize the sterilization effectiveness in the next process step. The pallets in the preconditioning vessel undergo several nitrogen fill/vacuum purges. Steam is supplied to this chamber by an exempt boiler which is fired only with natural gas at a maximum heat input rate of 2.1 MMBTU/hr. (Stack SB). This vessel exhausts uncontrolled through Stack B. Items are kept in this type of room for several hours or several days depending on sterilization requirement**.** <u>Sterilization Chambers</u> There will be five (5) ethylene oxide sterilization chambers at the facility, consisting of one sterilization line (Chamber #1) and 4 single chamber sterilization units. The pallets are moved into one of the five sterilization chambers. Chamber # 1 is rated at a capacity of 24 pallets. Chamber #2 is rated at a capacity of 6 pallets. Chamber #3 is rated at a capacity of 12 pallets. Chamber #4 is rated at a capacity of 6 pallets. Chamber #5 is rated at a capacity of 12 pallets. Material going to the sterilization line (Chamber #1) moves via a large enclosed conveyor (referred to as transfer bay #1). Transfer Bay # 1 is purged with nitrogen and exhausts the nitrogen uncontrolled through Stack G. After pallets of items to be sterilized are loaded into a chamber, a vacuum pump evacuates the air inside the chamber. The temperature and humidity levels are then adjusted as desired. Nitrogen gas is typically charged into the chamber to displace any remaining air. EtO gas is metered and pumped into the chamber. The liquid vaporizes immediately. The sterilization takes several hours while the chamber is sealed (no exhaust). Each chamber is evacuated several times by a series of 'pulls' with the chamber's

vacuum pump. The first of these 'pulls' removes the majority of the EtO gases from the chamber. There are several 'charges and pulls' using Nitrogen gas to purge most of the remaining EtO gas out of the chamber. The final 'charge and pull' is typically with ambient air. The vacuum 'pulls' are vented to the sterilization chambers' wet scrubber.

When chamber #1 completes the purging cycles, the doors are opened and the pallets are conveyed into transfer bay #2. The chamber doors then close back. Transfer bay #2 is vented to the aeration rooms' catalytic oxidizer to control the emissions.

When chambers #2 - #5 have been evacuated, the chamber door is cracked open. The chamber's exhaust fan is turned on and the chamber is vented to ambient air without air pollution control. Each of the exhaust fans has a capacity of approximately 1000 cubic feet per minute (cfm). However, a portion of the EtO emissions are assumed to vent through the open door to the atmosphere without the use of any air pollution controls.

Aeration Rooms

The pallets from all five (5) chambers are placed inside one of the five (5) aeration rooms (off gassing rooms) for continued venting of any residue of EtO. Each room has its temperature and humidity controlled as needed. Aeration rooms #1 – #3a/3b operates at approximately 115°F. Aeration room #4 is a cold aeration room. The product flow will utilize all aeration rooms depending on the specific requirements of various clients.

Aeration room #1 and #2 are vented by the same ventilation fan system that re-circulates a portion of the vented air back into the rooms while venting the remainder to the catalytic oxidizer (Abator). The EtO levels in the exhaust can range from 1 to 700 ppmv.

Aeration room #3a, #3b and #4 are on a separate ventilation fan system that will maintain the rooms at lower EtO concentrations. These rooms will be vented to the dry bed scrubber for reducing EtO emissions.

Wet Scrubber

Emissions from all the sterilization chambers' vacuum 'pulls' are controlled by a Damas Tri-Phase Model 1000 scrubber that exhausts through Stack C. The Damas scrubber uses a solution of sulfuric acid and water to control EtO emissions from the sterilization chambers. The acidic scrubbing liquor is used to reduce the amount of EtO vapor emitted. The acid content greatly enhances the conversion of EtO to Ethylene Glycol in water.

$$C_2H_4O\ (EtO) + H_2O \rightarrow HOCH_2CH_2OH\ (Ethylene\ Glycol)$$

The height of the liquor in the scrubber tank is maintained below 76 inches. The liquid is maintained at a pH of less than 1.5. The scrubber has two (2) connected acid scrubbing liquor tanks consisting of a 1,500 gallon and an up to 5,000 gallon tank. A pump is used to circulate the solution between the two tanks. The tanks have secondary containment and a leak alarm. A pump continuously circulates liquid from the scrubber through a heat exchanger. Following the heat exchanger, the scrubbing solution is circulated to the Damas scrubber. The acid scrubber meets the requirements of 40 CFR 63 Subpart O of 99% EtO emission Reduction.

	Catalytic Oxidizer Emissions from transfer bay #2 and aeration rooms #1 and #2 are controlled at an efficiency of 99.85% by a Donaldson Company, Inc., Model 2000 EtO-Abator® System (catalytic oxidizer) and exhaust through Stack CO at a design rate of 2,000 SCFM. The oxidizer, when operating is only fired with natural gas at a maximum heat input rate of 0.4 MMBTU/hr. Dry Bed Scrubber Emissions from aeration room #3a, #3b and #4 are vented to the up to 24,000 acfm DMS Advanced Air Technologies, Inc. dry bed scrubber for reducing EtO emission by the less stringent level of 1 ppmv or by at least 99% as required by 40 CFR 63.362(d). The design of the ventilation system will allow for up to 0% to 100% recirculation of the gases exiting the dry bed scrubber. The scrubber will have up to twelve (12) 2,000 acfm modules in parallel and manifolded into one stack that exhausts to the atmosphere. *Note: EtO possesses several physical and health hazards that merit special attention. EtO is both flammable and highly reactive. Acute exposures to EtO gas may result in respiratory irritation and lung injury, headache, nausea, vomiting, diarrhea, shortness of breath, and cyanosis. Chronic exposure has been associated with the occurrence of cancer, reproductive effects, mutagenic changes, neurotoxicity, and sensitization. http://www.osha.gov/SLTC/ethyleneoxide/index.html*

PERFORMANCE RESTRICTIONS

A.1. Federal Regulatory Requirements: This emission unit is subject to 40 CFR 63, Subpart O – Ethylene Oxide Emissions Standards for Sterilization and 40 CFR 63 Subpart A – General Provisions, which are adopted by reference in Rule 62-204.800, F.A.C.
[Rule 62-204.800(11), F.A.C.]
(See Attached Applicability Tables)

A.2. Permitted Capacity: The permittee shall not exceed a daily maximum usage rate of 1830 pounds of EtO and an annual maximum usage of 197.4 ton of EtO.
[Rules 62-210.200 (Definition of Potential to Emit), F.A.C.; As requested by permittee in letter dated October 4, 2011]

A.3. Operational Requirements:

The permittee shall not:

a. Operate the Damas scrubber's liquid outside the levels of 40" (initial charge) and 76"(maximum design) inches deep or higher than the level (site-specific operating parameter) established during the most recent compliance test.

b. Remove scrubber liquid (or partial transfers) in order to stay below the site-specific operating parameter established during the most recent compliance test. (Can add acid to control pH)

c. Have a device which reduces the vertical momentum or dispersion of the sterilization chambers scrubber exhaust (4 inches diameter & 58 feet height) and oxidizer exhaust (18 inches diameter & 19 feet height).

The permittee shall comply with the following:

d. The vacuum pump for the sterilization unit shall shut down if the pressure in the line goes above 10 psi.

e. Operational parameters and procedures for the scrubber:

   i. The liquid sensor in the dike surrounding the scrubber shall sound an alarm if more than 1/8 of an inch of liquid is present.

   ii. An alarm will sound if the re-circulating pump drops below a designated target point.

   iii. An alarm will sound if the temperature of the cooled scrubbing solution goes above 90° F.

f. The dry scrubber manufacturer's specifications. See *Specific Condition A.17.b.*

(Permitting note: See Appendix D, Condition 1, for Operation Rate during testing requirements.)

[Rules 62-4.070(3) and 62-4.160(2), F.A.C.; revised permit application received 9/22/2011]

A.4. Ethylene Oxide (EtO) Control Efficiency:

a. The wet scrubber shall reduce EtO emissions by at least 99%.

b. The catalytic oxidizer shall reduce EtO emissions to a maximum concentration of 1 ppmv or at least 99% whichever is less.

c. The dry bed scrubber shall reduce EtO emissions to a maximum concentration of 1 ppmv or at least 99% whichever is less.

[Rules 62-4.160(2), and, 62-210.200 (Definition of Potential to Emit), F.A.C.; 40 CFR 63.362(c) & (d); permit applications received 8/17/2011 and 3/15/2012]

A.5. Permitted Fuels: The catalytic oxidizer shall be only fired with natural gas.
[Rule 62-213.410, F.A.C.; Construction Permit 1030197-010-AC]

(Permitting Note - The oxidizer's manufacturer specifications state the maximum heat input from natural gas usage is 0.4 MMBTU/hr. Based on the fuel type used and the design maximum fuel usage rate along with the type of process the oxidizer is controlling, visible emissions from the oxidizer are not expected to be emitted.)

A.6. Hours of Operation: The hours of operation are not limited (8760 hours per year).
[Rules 62-4.070(3) and 62-210.200(PTE), F.A.C.]

EMISSIONS STANDARDS

A.7. Emission Limitations: The total EtO emissions from the sterilization process, including emissions from the scrubber stack, catalytic oxidizer stack, and fugitive emissions from opening doors shall not exceed 4.0 tons per any 12 consecutive months.

(Permitting Note: The emission limit for EtO (4.0 tons/year) in combination with EtO emissions from the exempt emission sources and activities will be below the Title V threshold of 10 tons/year for a

single HAP. Due to the nature of this business additional Total HAPs and VOC emissions limits are not necessary.)

[Rule 62-210.200 (Definition of Potential to Emit), F.A.C.]

TESTING REQUIREMENTS

A.8. Initial Compliance Tests:

a. The emissions unit shall be tested to demonstrate compliance with the Ethylene Oxide Control Efficiency (for the wet scrubber, dry bed scrubber and catalytic oxidizer). The tests shall be conducted no later than 90 days after initial operation for each of the four new sterilization chambers and/or the dry bed scrubber.

b. In addition to the stack testing required by a. above, the ethylene oxide concentration inside the sterilization chambers shall be tested during normal operation (maximum charge) at the end of the sterilization cycle, just prior to removing the pallets from the chamber in order to verify or refine the fugitive emission estimates from chambers #1 - #5.

[Rules 62-4.070(3) and 62-297.310(7)(a)1, F.A.C.]

A.9. Compliance Tests After Initial Testing: During each federal fiscal year (October 1st to September 30th), the emissions unit shall be tested to demonstrate compliance with Ethylene Oxide Control Efficiency.
[Rule 62-297.310, F.A.C.]

A.10. Test Requirements:

a. Tests shall be conducted in accordance with the methods and procedures of 40 CFR 63, Subpart O (see Specific Condition A.11.), and in accordance with the applicable requirements specified in Appendix D (Common Testing Requirements) of this permit.

b. The compliance tests shall be conducted with all chambers operating without pallets at 90 – 100% of capacity. The emissions from all chambers must vent to the control scrubber simultaneously. For testing purposes the maximum capacity of each chamber is:

Chamber #	Maximum EtO usage/ cycle (lbs)
1	170
2	75
3	145
4	75
5	145

c. Compliance tests on the catalytic oxidizer shall be conducted prior to changing the oxidizer's catalyst or adding make-up catalyst. Additionally, the tests shall not be conducted within 90 days after the oxidizer's catalyst is either changed or make-up catalyst is added.

[Rules 62-4.070 and 62-297.310, F.A.C.]

A.11. Test Method(s): Required tests shall be performed in accordance with the following reference method(s).

Method(s)	Description of Method and Comments
2,2A,2C, or 2D	Determination of Stack Gas Velocity and Volumetric Flow Rate.
18 or 25A	Determination of Total Gaseous Organic Concentration using Gas Chromatography or Flame Ionization Analyzer.

The above method(s) are described in Appendix A of 40 CFR 60 and are adopted by reference in Rule 62-204.800, F.A.C. No other method(s) may be used unless prior written approval is received from the Department.
[Rules 62-204.800 and 62-297.100, F.A.C.; and Appendix A of 40 CFR 60]

NOTIFICATION REQUIREMENTS

A.12. Test Notification: The permittee shall notify the Compliance Authority (PCAQD) in writing at least 60 days prior to any required tests. The notification must include the following information: the date, time and location of each test; the name and telephone number of the facility's contact person who will be responsible for coordinating the test; and the name, company, and the telephone number of the person conducting the test.

{*Permitting Note: The notification should also include the relevant emission unit ID No(s)., test method(s) to be used, and pollutants to be tested.*}
[Rule 62-297.310(7)(a)9., F.A.C.; 40 CFR 63.7]

A.13. Notification of Operation Commencement: The permittee shall notify the Compliance Authority (PCAQD) in writing of the date of commencing operation of each of the four (4) new sterilization chambers and the dry bed scrubber, no later than fifteen (15) days after that date. Commencing operation means setting into operation of any emissions unit for any purpose.
[Rule 62-4.070, F.A.C., and Rule 62-210.200, F.A.C., (Definition of Commence Operation)]

A.14. Notification of Renovation/Demolition: If there are any activities during the installation of the new sterilization units that meet the definitions of renovation or demolition activities under 62-257 F.A.C. (Asbestos Program) or Pinellas County Code 58-146 through 149 the permittee shall ensure that asbestos surveys, notifications and removals are properly conducted under those rules. Compliance assistance is available at the Pinellas County website. http://www.pinellascounty.org/environment/airquality/default.htm, or by calling Pinellas County at 727-464-4422.
[Rule 62-257, F.A.C.; Pinellas County Code §58-146 through 149]

RECORDS AND REPORTS

A.15. Test Reports: The permittee shall prepare and submit reports for all required tests in accordance with the requirements specified in Appendix D (Common Testing Requirements)

of this permit. Emission compliance test reports shall be submitted to the Air Quality Division of the PCAQD within 45 days of testing.

Failure to submit the following with any test reports may invalidate the tests and fail to provide reasonable assurance of compliance.

a. A copy of the operator's Operation and Maintenance records for the wet scrubber, dry scrubber and catalytic oxidizer for the test day.

b. The EtO usage rate for each test run.

c. A statement indicating the scrubber's liquid tank level during each run and the new established liquid tank level (operating parameter).

d. Documentation of compliance with Specific Condition A.10.c. (such as the date(s) the catalyst was last changed and/or planned to be changed and make-up catalyst was last added and/or is planned to be added) with this requirement shall be provided with each test report.

e. One reading of each operating parameter required by the Operation and Maintenance Manual for each run. *See Specific Condition A.17.*

[Rule 62-297.310, F.A.C.]

A.16. Operating Log: The permittee shall maintain the following records to demonstrate compliance with Specific Condition A.2. and A.7.

Daily:

a. The date, Facility ID, and Emission Unit No. & Description (i.e., 1030197, EU 001-Ethylene Oxide Sterilization Unit);

b. The ethylene oxide (EtO) usage rate for the day (pounds/day); and

c. The maximum and minimum liquid levels for the Damas scrubber for the day (inches); and

d. The EtO concentration of the dry bed scrubber outlet as measured by the detector tube .

Monthly:

e. The month, Facility ID, and Emission Unit No. & Description (i.e., 1030197, EU 001-Ethylene Oxide Sterilization Unit);

f. The ethylene oxide (EtO) usage rate for the month (pounds/month); and

g. The most recent consecutive 12-month totals of ethylene oxide (EtO) usage; and

h. The most recent consecutive 12-month totals of ethylene oxide (EtO) emissions.

(Permitting Note: See also the Monitoring, Recordkeeping and Reporting Requirements in Appendix 40 CFR 63 Subpart O.)

Daily records shall be completed within five (5) calendar days and monthly records shall be completed by the end of each following month. These records shall be retained on file at the facility for at least three (3) years and shall be made available to the Department and the Pinellas County Air Quality Division (PCAQD) upon request.

[Rule 62-4.070(3), F.A.C.; permit application received 8/17/2011]

OPERATION AND MAINTENANCE PLAN

A.17. Operation and Maintenance (O & M) Plan for Ethylene Oxide Emission Control: The permittee shall maintain and implement the Operation and Maintenance (O&M) Plan for the Damas Tri Phase Model 1000 Scrubber and the Donaldson EtO Catalytic Abator Model 2000, submitted on September 6, 2011, or as revised with the prior approval from the PCAQD. The O&M Plan documentation shall be retained at the facility and made available to the Department and PCAQD upon request. At a minimum, the O&M plan shall include:

a. The operating parameters of the pollution control device.

b. Time table for the routine maintenance of the pollution control device as specified by the manufacturer.

c. Time table of routine daily, weekly, bi-weekly, or monthly observations and inspections of the pollution control device.

d. A list of the type and quantity of the required spare parts for the pollution control device which are stored on the premises.

e. A maintenance log which will indicate, as a minimum:

1. When maintenance and observations were performed.
2. What maintenance and observations were performed.
3. Who performed said maintenance and observations.
4. Acceptable parameter ranges for each operational check.

(Note: The Operation and Maintenance (O & M) Plan for dry bed scrubber will be submitted with the operating permit application.)

[Pinellas County Code, Section 58-128]