



FLORIDA DEPARTMENT OF ENVIRONMENTAL PROTECTION

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

RICK SCOTT
GOVERNOR

HERSCHEL T. VINYARD JR.
SECRETARY

May 14, 2013

FINAL PERMIT

PERMITTEE

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

Air Permit No. 1030197-018-AF
Permit Expires: **05/14/2018**
Site Name : Synergy Health AST, LLC
Federally Enforceable State Operation Permit
(FESOP) Renewal

Authorized Representative:
Mr. Ray Aaron, Plant Manager

This is the final permit to renew Air Operation Permit No. 1030197-014-AF and incorporate emissions sources and associated requirements from Air Construction Permit No. 1030197-016-AC for an ethylene sterilization chamber that is used to sterilize custom surgical pallets for the health care industry as well as other medical supplies at the Synergy Health AST, LLC – Oldsmar Facility (Standard Industrial Classification No. 5047). The facility is located in Pinellas County at 401 Commerce Blvd. 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 draft 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.

A person whose substantial interests are affected by the proposed permitting decision may petition for an administrative proceeding (hearing) under sections 120.569 and 120.57 of the Florida Statutes. The petition must contain the information set forth below and must be filed (received) in the Office of General Counsel of the Department at 3900 Commonwealth Boulevard, Mail Station #35, Tallahassee, Florida 32399-3000. Petitions filed by the permit applicant or any of the parties listed below must be filed within fourteen days of receipt of this notice of final permit. Petitions filed by any persons other than those entitled to written notice under section 120.60(3) of the Florida Statutes must be filed within fourteen days of publication of the public notice or within fourteen days of receipt of this notice of final permit, whichever occurs first. Under section 120.60(3), however, any person who asked the Department for notice of agency action may file a petition within fourteen days of receipt of that notice, regardless of the date of publication. A petitioner shall mail a copy of the petition to the applicant at the address indicated above at the time of filing. The failure of any person to file a petition within the appropriate time period shall constitute a waiver of that person's right to request an administrative determination (hearing) under sections 120.569 and 120.57 F.S., or to intervene in this proceeding and participate as a party to it. Any subsequent intervention will be only at the approval of the presiding officer upon the filing of a motion in compliance with rule 28-106.205 of the Florida Administrative Code.

All petitions filed under these rules shall contain:

- (a) The name and address of each agency affected and each agency's file or identification number, if known;
- (b) The name, address, and telephone number of the petitioner; the name, address, and telephone number of the petitioner's representative, if any, which shall be the address for service purposes during the course of the proceeding; and an explanation of how the petitioner's substantial interests will be affected by the agency determination;
- (c) A statement of when and how the petitioner received notice of the agency decision;
- (d) A statement of all disputed issues of material fact. If there are none, the petition must so indicate;
- (e) A concise statement of the ultimate facts alleged, including the specific facts the petitioner contends warrant reversal or modification of the agency's proposed action;
- (f) A statement of the specific rules or statutes the petitioner contends require reversal or modification of the agency's proposed action, including an explanation of how the alleged facts relate to the specific rules or statutes; and
- (g) A statement of the relief sought by the petitioner, stating precisely the action petitioner wishes the agency to take with respect to the agency's proposed action.

A petition that does not dispute the material facts upon which the Department's action is based shall state that no such facts are in dispute and otherwise shall contain the same information as set forth above, as required by rule 28-106.301 of the Florida Administrative Code.

Because the administrative hearing process is designed to formulate final agency action, the filing of a petition means that the Department's final action may be different from the position taken by it in this notice. Persons whose substantial interests will be affected by any such final decision of the Department on the application have the right to petition to become a party to the proceeding, in accordance with the requirements set forth above.

Mediation is not available in this proceeding.

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, 3900 Commonwealth Boulevard, Mail Station #35, 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 thirty days after this order is filed with the clerk of the Department.

Executed in Hillsborough County, Florida

Kelley M. Boatwright 05/13/2013
Kelley M. Boatwright 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 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 the date indicated below to the persons listed below.

- Mr. Ray Aaron, Authorized Representative, Synergy Health AST, LLC (raaron@beam-one.com)
- Mr. Robert A. Baker, Baker Environmental Engineering, Inc. (baker@atlantic.net)
- Mr. Gary Robbins, PCAQD, (grobbins@co.pinellas.fl.us)

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.

Cerna Brathy May 14, 2013
(Clerk) (Date)

SECTION 1. GENERAL INFORMATION FINAL

FACILITY AND PROJECT DESCRIPTION

Existing Facility

This facility consists of the operation of a three ethylene oxide sterilization chambers that is used to sterilize custom surgical pallets for the health care industry as well as other medical supplies. The facility consists of the following emissions unit (EU).

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

Exempt Emission Units/Activities

- 2.1 MM Btu/hr Natural Gas Boiler [Rule 62-210.300(3)(a)(2) and (3), F.A.C.]

The following emissions units are subject to Rule 62-210.300(3)(a)35. - Categorical and Conditional Exemptions – Stationary Reciprocating Internal Combustion Engines, F.A.C.

- 375 HP Emergency Generator – Diesel Fired
- 244 HP Fire Pump Engine – Diesel Fired

(Federal Rule Applicability Permitting Note – The above engines are subject to requirements of Federal NESHAP 40 CFR 63, Subpart ZZZZ, National Emissions Standards for Hazardous Air Pollutants (NESHAP) for Stationary Reciprocating Internal Combustion Engines as they apply to stationary emergency compression ignition engines at area sources of hazardous air pollutants (HAPs).

The following emissions units are subject to Rule 62-210.300(3)(b)1. – Generic Emissions Unit or Activity Exemption, F.A.C.

- Ethylene Oxide Tanks
- Paved roadways, parking lots, truck loading and unloading operations
- Chemical/solvent/waste storage drums
- Fugitives from minor spills or leaks
- Tank degassing and cleaning

FACILITY REGULATORY CLASSIFICATION

- The facility is not a major source of hazardous air pollutants (HAPs).
- 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 Volatile Organic Compounds (VOC) and HAPs (Hazardous Air Pollutants). The emission limitations and restriction on the amount of material used in this

SECTION 1. GENERAL INFORMATION FINAL

permit will ensure that the facility's VOC and HAP emissions will be below the threshold for a Title V source.

- The ethylene oxide sterilization process is regulated under National Emissions Standards for Hazardous 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

This permit replaces the Federally Enforceable State Operation Permit (FESOP) No. 1030197-014-AF and partially incorporates terms and conditions of Construction Permit No. 1030197-016-AC.

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

ADMINISTRATIVE REQUIREMENTS

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

The Pinellas County Air Quality Division
509 East Avenue South, Suite 138
Clearwater, Florida 33760
Telephone: 727-464-4422

All documents related to compliance activities such as reports, tests, and notifications shall be submitted to the above address.

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.]

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

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. **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.]
8. **Operation Permit Renewal Application** - A completed application for renewal of the operation permit shall be submitted to the Permitting Authority with a copy to the Pinellas County Air Quality Division (Compliance Authority) no later than 60 days prior to the expiration date of this operation permit. To properly apply for an 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.;
 - c. copies of the most recent compliance test reports required by Specific Condition No. A.13., if not previously submitted;
 - d. copies of the most recent two months of records/logs specified in Specific Condition No. A.14.; and
 - e. any proposed revisions to the most recently approved O & M Plan (PCAQD), if applicable.
- [Rules 62-4.030, 62-4.050, 62-4.070(3), 62-4.090, 62-210.300(2), and 62-210.900, F.A.C.]

FACILITY-WIDE SPECIFIC CONDITIONS

9. **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.]
10. **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]

SECTION 3. EMISSION UNIT SPECIFIC CONDITIONS (FINAL)

A. EU No. 001 - Ethylene Oxide Sterilization Units

This section of the permit addresses the following emissions unit (EU).

EU ID No.	Emission Unit Description
001	<p><u>Ethylene Oxide Sterilization Process</u></p> <p>Synergy Health has several steps in the sterilization process. Chamber 1 is a sterilization line consisting of multiple chambers where the various sterilization steps are processed. Chambers 2 and 3 are single chambers, where all the steps are done in the chamber.</p> <ul style="list-style-type: none"> • Items to be sterilized are preconditioned 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. <p><u>Preconditioning</u></p> <p>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.</p> <p><u>Sterilization Chambers</u></p> <p>There are currently three (3) ethylene oxide sterilization chambers operating at the facility. They consists of one sterilization line (Chamber #1) and Chambers #2 and #3 single chamber sterilization units. The pallets are moved into one of the three sterilization chambers. (<i>Note – Two additional sterilization chambers are pending construction under Construction Permit No. 1030197-016-AC.</i>)</p> <p style="padding-left: 40px;">Chamber # 1 is rated at a capacity of 24 pallets.</p> <p style="padding-left: 40px;">Chamber #2 is rated at a capacity of 6 pallets.</p> <p style="padding-left: 40px;">Chamber #3 is rated at a capacity of 12 pallets.</p> <p>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.</p> <p>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.</p> <p>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).</p> <p>Each chamber is evacuated several times by a series of ‘pulls’ with the chamber’s vacuum</p>

SECTION 3. EMISSION UNIT SPECIFIC CONDITIONS (FINAL)

A. EU No. 001 - Ethylene Oxide Sterilization Units

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 & #3 have been evacuated after several "pulls" are vented to the wet scrubber, the chamber doors are cracked open. The chambers' exhaust fan is turned on and the chambers are 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 the existing three (3) 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. Note: Aeration Room #4 has been installed, but has not yet in operation.

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 are 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.



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 (Sterilization Line Chamber 1) and Aeration Rooms #1 and #2 are controlled at an efficiency of 99.85% by a Donaldson Company, Inc., Model 2000

SECTION 3. EMISSION UNIT SPECIFIC CONDITIONS (FINAL)

A. EU No. 001 - Ethylene Oxide Sterilization Units

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 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 allows for up to 0% to 100% recirculation of the gases exiting the dry bed scrubber. The scrubber currently has five (5) 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 National Emission Standard for Hazardous Air Pollutants (NESHAP) 40 CFR 63 Subpart O – Ethylene Oxide Emissions Standards for Sterilization and 40 CFR 63 Subpart A – General Provisions, which is adopted by reference in Rule 62-204.800(11), F.A.C. (See NESHAP Subpart O and Subpart A Applicability Tables which are attached to and made a part of this permit)
[Rule 62-204.800(11), F.A.C.]

A.2. Permitted Capacity – The permittee shall not exceed a daily maximum usage rate of 1,170 pounds of EtO and a maximum usage of 126.2 tons of EtO in any consecutive 12-month period.

(Permitted Capacity Permitting Note – The above are the maximum permitted process rate limitations for the three currently operational sterilization chambers, Chambers 1, 2, and 3.)

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

[Rule 62-210.200 (Definition of Potential to Emit), F.A.C., Construction Permit No. 1030197-016-AC]

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)

SECTION 3. EMISSION UNIT SPECIFIC CONDITIONS (FINAL)

A. EU No. 001 - Ethylene Oxide Sterilization Units

- 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 recommended maintenance requirements. (*See Specific Condition A.16.b.*)
- g. When the monitored value of EtO, as confirmed by additional sampling, reaches 1.0 ppm of EtO (*see Specific Condition A.14.d.*), the dry bed scrubber will then be taken out of service and the scrubber's absorption material changed.

[Rules 62-4.070(3) and 62-4.160(2), F.A.C.; Permit Application dated 03/26/2013; Construction Permit No. 1030197-016-AC; Operation Permit Renewal Application received 03/26/13]

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

- a. The 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); Construction Permit No. 1030197-016-AC]

A.5. Permitted Fuels: The catalytic oxidizer shall be only fired with natural gas.

[Rule 62-213.410, F.A.C.; Construction Permit 1030197-016-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. Restricted Operation - The hours of operation are not limited (i.e., permitted for 8760 hours per year).

[Rules 62-4.070(3) and 62-210.200 (definition of Potential to Emit), F.A.C. Construction Permit No. 1030197-016-AC]

EMISSIONS STANDARDS

SECTION 3. EMISSION UNIT SPECIFIC CONDITIONS (FINAL)

A. EU No. 001 - Ethylene Oxide Sterilization Units

A.7. Emission Limitations - The total EtO emissions from the existing sterilization line, 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.; Construction Permit No. 1030197-016-AC]

COMPLIANCE TESTING REQUIREMENTS

A.8. Compliance Tests - During each federal fiscal year (October 1st to September 30th), the emissions unit shall be tested to demonstrate compliance with the emissions standards for Ethylene Oxide Control Efficiency.

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

A.9. Compliance Test Requirements –

- a. Compliance tests shall be conducted in accordance with the methods and procedures of 40 CFR 63, Subpart O (see Specific Condition A.10.), 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 Chambers #1, #2, and #3 operating without pallets at 90 – 100% of capacity. The emissions from the referenced 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

- 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.

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

A.10. Compliance Test Methods - Required compliance tests shall be performed in accordance with the following reference methods.

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.

SECTION 3. EMISSION UNIT SPECIFIC CONDITIONS (FINAL)

A. EU No. 001 - Ethylene Oxide Sterilization Units

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 methods may be used unless prior written approval is received from the Department.

[Rule 62-204.800 and 62-297.100, F.A.C.; and Appendix A of 40 CFR 60]

NOTIFICATION REQUIREMENTS

- A.11. Test Notification** - The permittee shall notify the Compliance Authority 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.)

[Rules 62-4.070(3) and 62-297.310(7)(a)9., F.A.C., Subpart A 40 CFR 63.7]

- A.12. Notification of Renovation/Demolition** - If there are any activities during the installation of the remaining two chambers in the sterilization unit that meets 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]

RECORDKEEPING AND REPORTING REQUIREMENTS

- A.13. Compliance Test Reports** - The permittee shall prepare and submit reports for all required compliance 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.9.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.

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- e. One reading of each operating parameter required by the Operation and Maintenance Manual for each run. *See Specific Condition A.15. and A.16.*

[Rule 62-297.310(8), F.A.C.]

- A.14.** Daily, Weekly and/or Monthly EtO 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).

Weekly (or Daily):

- d. the EtO concentration of the dry bed scrubber outlet as measured by the detector tube until a reading of 0.8 ppm EtO is reached. Once the dry bed scrubber reading has reached 0.8 ppm EtO, then the scrubber exhaust will be monitored daily during normal working hours until a reading of 1.0 ppm of EtO is obtained and confirmed. (*See Specific Condition A.3.g. for associated dry bed scrubber operating requirements.*).

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 within ten (10) calendar days of the end of each 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.; Construction Permit 1030197-018-AC; Operation Permit Renewal Application received 03/26/13]

- A.15.** Operation and Maintenance (O & M) Plan for Ethylene Oxide Emission Control - The permittee shall maintain and implement the 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.

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- 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.

[Pinellas County Code, Section 58-128]

A.16. Operation and Maintenance (O&M) Plan for Dry Scrubber – The permittee shall submit a revised Operation and Maintenance Plan (O & M Plan) for the Advanced Air Technologies, Inc. DR490 dry bed scrubber **within 60 days of receipt of this permit**. The revised plan must specify specific timelines for all maintenance and observations and must include an O&M log that includes the checks from the O&M Plan, along with the frequencies, parameter limits, observations, etc. (see Item e. below). The facility shall maintain and implement the O&M Plan for the dry scrubber as approved by Pinellas County. The plan may be 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.

[Pinellas County Code, Section 58-128]