



DEPARTMENT ORDER

**The Jackson Laboratory
Hancock County
Ellsworth, Maine
A-1127-71-D-A**

**Departmental
Findings of Fact and Order
Air Emission License
Amendment #3**

FINDINGS OF FACT

After review of the air emission license amendment application, staff investigation reports, and other documents in the applicant's file in the Bureau of Air Quality, pursuant to 38 Maine Revised Statutes (M.R.S.) § 344 and § 590, the Maine Department of Environmental Protection (Department) finds the following facts:

I. REGISTRATION

A. Introduction

The Jackson Laboratory (JAX) was issued Air Emission License A-1127-71-A-N on April 28, 2017, for the operation of emission sources associated with their mouse production facility. The license was subsequently amended on May 9, 2018 (A-1127-71-B-M) and on April 1, 2019 (A-1127-71-C-A).

JAX has requested an amendment to their license in order to install a second ethylene oxide (EtO) sterilizer.

The equipment addressed in this license amendment is located at 21 Kingsland Crossing, Ellsworth, Maine.

B. Emission Equipment

The following equipment is addressed in this air emission license amendment:

Process Equipment

| Equipment | Chamber Capacity | Process Rate | Pollution Control Equipment |
|-------------------|-------------------------|---------------------|------------------------------------|
| EtO Sterilizer #2 | 7.9 ft ³ | 170 g EtO/batch | Catalytic Oxidizer (Abator) |

C. Application Classification

All rules, regulations, or statutes referenced in this air emission license refer to the amended version in effect as of the date this license was issued.

The modification of a minor source is considered a major or minor modification based on whether or not expected emission increases exceed the “Significant Emission” levels as defined in the Department’s *Definitions Regulation*, 06-096 Code of Maine Rules (C.M.R.) ch. 100. This modification will not result in any emissions increases of any criteria pollutant. It has been determined to be a minor modification and has been processed as such.

D. Facility Classification

With the annual operating hours restriction on the emergency generators, the facility is licensed as follows:

- As a synthetic minor source of air emissions, because JAX is subject to license restrictions that keep facility emissions below major source thresholds for criteria pollutants; and
- As an area source of hazardous air pollutants (HAP), because the licensed emissions are below the major source thresholds for HAP.

II. **BEST PRACTICAL TREATMENT (BPT)**

A. Introduction

In order to receive a license, the applicant must control emissions from each unit to a level considered by the Department to represent Best Practical Treatment (BPT), as defined in *Definitions Regulation*, 06-096 C.M.R. ch. 100. Separate control requirement categories exist for new and existing equipment.

BPT for new sources and modifications requires a demonstration that emissions are receiving Best Available Control Technology (BACT), as defined in *Definitions Regulation*, 06-096 C.M.R. ch. 100. BACT is a top-down approach to selecting air emission controls considering economic, environmental, and energy impacts.

B. EtO Sterilizer #2

JAX has proposed the installation of a 3M™ Steri-VAC GS8X ethylene oxide (EtO) sterilizer with a chamber capacity of 7.9 cubic feet (EtO Sterilizer #2).

EtO Sterilizer #2 will use sealed EtO cartridges that are only punctured once the cartridge is inside the locked, sealed sterilization chamber, minimizing the potential for EtO leaks. The EtO cartridges are single-use and contain 170 grams of EtO each.

1. BACT Findings

EtO Sterilizer #2 will emit EtO which is both a VOC and a HAP.

EtO emissions can be controlled using add-on pollution control equipment such as wet scrubbers, catalytic oxidizers, or condensers, all three of which can achieve control efficiencies greater than 99%. Wet scrubbers produce a wastewater effluent that requires disposal and/or treatment. Condensers also produce a by-product ethylene oxide stream which would require disposal and treatment.

JAX proposes to install a catalytic oxidizer known as an abator. The abator converts the EtO exhausted from the sterilization unit into carbon dioxide and water vapor. The exothermic reaction occurs in the presence of a proprietary catalyst and has an EtO destruction efficiency of 99.9%. Operating continuously with the catalytic oxidizer, EtO Sterilizer #2 has the potential to emit less than 10 pounds per year of EtO which is half of the insignificant emissions threshold for EtO as identified in 06-096 C.M.R. ch. 115, Appendix B(C).

Visible emissions from EtO Sterilizer #2 shall not exceed 10% opacity on a six (6) minute block average basis.

BACT for EtO Sterilizer #2 shall be operation and maintenance of the unit and its catalytic oxidizer according to the manufacturer's specifications.

JAX shall keep records for EtO Sterilizer #2 and the associated catalytic oxidizer of all maintenance performed including dates and details of what work was performed. JAX shall also keep records of the number of batches processed between catalytic oxidizer replacements.

2. National Emission Standards for Hazardous Air Pollutants

JAX is not subject to *National Emission Standards for Hospital Ethylene Oxide Sterilizers*, 40 C.F.R. Part 63, Subpart WWWW as JAX does not provide medical care and treatment for patients under supervision of licensed physicians or under nursing care. Therefore, JAX does not meet the definition of a hospital and is not subject to this subpart.

JAX is not subject to *Ethylene Oxide Emissions Standards for Sterilization Facilities*, 40 C.F.R. Part 63, Subpart O as JAX does not have the potential to use more than 1.0 ton/year of EtO. In addition, JAX is further exempt from this regulation as it is a research or laboratory facility as defined in the *Clean Air Act Amendments of 1990*, § 112(C)(7).

C. Annual Emissions

This amendment does not change any annual emissions from the facility used for fee purposes.

ORDER

Based on the above Findings and subject to conditions listed below, the Department concludes that the emissions from this source:

- will receive Best Practical Treatment,
- will not violate applicable emission standards, and
- will not violate applicable ambient air quality standards in conjunction with emissions from other sources.

The Department hereby grants Air Emission License Amendment A-1127-71-D-A subject to the conditions found in Air Emission License A-1127-71-A-N, in amendments A-1127-71-B-M and A-1127-71-C-A, and the following conditions.

Severability. The invalidity or unenforceability of any provision of this License Amendment or part thereof shall not affect the remainder of the provision or any other provisions. This License Amendment shall be construed and enforced in all respects as if such invalid or unenforceable provision or part thereof had been omitted.

SPECIFIC CONDITIONS

The following shall replace Condition (19) of Air Emission License A-1127-71-B-M:

(19) EtO Sterilizers #1 & #2

- A. EtO Sterilizers #1 & #2 and the associated catalytic oxidizers shall be operated and maintained according to the manufacturer's specifications.
[06-096 C.M.R. ch. 115, BACT]
- B. The associated catalytic oxidizer shall be operated at all times EtO Sterilizers #1 & #2 are in operation. [06-096 C.M.R. ch. 115, BACT]
- C. JAX shall keep records for EtO Sterilizers #1 & #2 and the associated catalytic oxidizers of all maintenance performed including dates and details of what work was performed. JAX shall also keep records of the number of batches processed in each machine between catalytic oxidizer replacements. [06-096 C.M.R. ch. 115, BACT]

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- D. JAX shall calculate VOC and HAP emissions on a calendar year basis based on the number of batches processed in each machine, ethylene oxide usage, and an oxidizer conversion efficiency of 99%. [06-096 C.M.R. ch. 115, BACT]
- E. Visible emissions from EtO Sterilizers #1 & #2 shall each not exceed 10% opacity on a six (6) minute block average basis. [06-096 C.M.R. ch. 115, BACT]

DONE AND DATED IN AUGUSTA, MAINE THIS 12th DAY OF February, 2020.

DEPARTMENT OF ENVIRONMENTAL PROTECTION

BY:

 Per
GERALD D. REID, COMMISSIONER

The term of this amendment shall be concurrent with the term of Air Emission License A-1127-71-A-N.

PLEASE NOTE ATTACHED SHEET FOR GUIDANCE ON APPEAL PROCEDURES

Date of initial receipt of application: 12/16/2019

Date of application acceptance: 12/19/2019

Date filed with the Board of Environmental Protection:

This Order prepared by Lynn Muzzey, Bureau of Air Quality.

