



UNITED STATES. Sullivan ENVIRONMENTAL PROTECTION
AGENCY
Region 1
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Clean Air Act Inspection Report

Drafted: July 28, 2023

Finalized: August 2, 2023

EPA Inspector: Davianna Vasconcelos, Environmental Engineer, Air Compliance Section /DMV/
Hannah Patel, Environmental Scientist, Air Compliance Section/HHP/

EPA Reviewer: Darren Fortescue, Manager, Air Compliance Section /DEF/

Date of Inspection: July 19, 2023

Facility Name: Covidien LP

ICIS Air ID#: CT0000000900905468

Facility Location: 195 McDermott Road, North Haven, CT 06473

Mailing Address: 60 Middletown Avenue, Mailstop 7, North Haven, CT 06473

Disclaimer:

Unless otherwise noted, this report describes conditions at the facility/property as observed by EPA inspector(s), and/or through records provided to and/or information reported to EPA inspector(s) by facility representatives and as understood by the inspector(s). This report may not capture all operations or activities ongoing at the time of the inspection. This report does not make final determinations on potential areas of concern. Nothing in this report affects EPA's authorities under federal statutes and regulations to pursue further investigation or action.

Inspection Attendees:

Name	Title	Organization
Davianna Vasconcelos	Environmental Engineer	EPA R1
Hannah Patel	Environmental Scientist	EPA R1
Fahim Ibrahim	Air Pollution Control Engineer	CT DEEP
Julian Taborda	Air Pollution Control Engineer	CT DEEP
Jennifer Shea	Principal Environmental Specialist	Covidien LP
Erin Sullivan	Senior Environment, Health & Safety Manager	Covidien LP
Benjamin Weidman	Environmental, Health & Safety Program Manager	Covidien LP
Kevin Sim	Lead Sterilization Technician	Covidien LP
Keane Regan	Sterilization Manager	Covidien LP
Renato Avallone	Sterilization Technician	Covidien LP

Facility/Process Description:

Covidien LP (“Covidien”), located at 195 McDermott Road North Haven, CT 06473, was established in 1982. The facility conducts research and development and manufactures and sterilizes surgical equipment. The facility footprint is approximately 1.6 million square feet.

The facility has two production sterilization chambers each with a primary aeration room attached. Both the sterilization chambers and primary aeration rooms are vented to a balancer/oxidizer system. The facility has two secondary aeration rooms that are currently vented to atmosphere. The facility plans to redirect emissions from secondary aeration into primary aeration and close the vent to the atmosphere. The facility plans to operate two vacuum degassers, that were installed but not operational at the time of the inspection, as an option for secondary aeration for specific products. The degassers will be vented to balancer/oxidizer system.

The facility has one research and development sterilizer that aerates within the chamber and is vented to the balancer/oxidizer system.

The facility has a balancer/oxidizer ethylene oxide (“EtO”) control system manufactured by LENS. The system was designed to control emissions for up to four sterilization chambers. The balancer uses water in a buffer tank and a stripper column to absorb high concentrations of EtO and equalize the concentration of EtO going to the catalytic oxidizer. The catalytic oxidizer is used to convert EtO into carbon dioxide and water.

Number of Employees and Working Hours:

The facility has approximately 2,900 employees.

The facility operates 24 hours a day, seven days a week.

Potentially Applicable Clean Air Act Requirements:

- 40 CFR Part 63 Subpart O - Ethylene Oxide Emissions Standards for Sterilization Facilities
- Connecticut New Source Review Permit #135-0143
- Connecticut New Source Review Permit #135-0144

Previous Enforcement Actions:

A “Detailed Facility Report” from EPA’s Enforcement and Compliance History Online database indicates that there have been no informal or formal enforcement actions taken against Covidien by EPA in the past five years.

EPA’s Enforcement and Compliance History Online database indicates that Connecticut Department of Energy and Environmental Protection issued a Notice of Violation to Covidien in December of 2020.

Opening Conference:

EPA representatives Davianna Vasconcelos and Hannah Patel arrived at the facility at 8:30am to meet Fahim Ibrahim and Julian Taborda of Connecticut Department of Energy and Environmental Protection. The group entered the facility and met Jennifer Shea, Erin Sullivan, and Benjamin Weidman of Covidien. The group proceeded to a conference room where Ms. Vasconcelos initiated an opening conference. Ms. Vasconcelos presented her credentials and explained the purpose of inspection was to review the facility's compliance with Subpart O requirements. Ms. Vasconcelos explained that if any information during the inspection should be considered proprietary, Covidien can submit a Confidential Business Information ("CBI") claim.

Facility Tour:

Ms. Shea led Ms. Vasconcelos, Ms. Patel, Mr. Ibrahim, Mr. Taborda, and Ms. Sullivan to Sterilization Control Room where the group met Kevin Sim, Keane Regan, and Renato Avallone of Covidien.

Mr. Sim said the two production sterilization chambers are manufactured by Environmental Tectonics Corporation and were installed in approximately 2015. Mr. Sim said each sterilizer has a 6-pallet capacity, uses approximately 25 lb EtO per cycle, and takes approximately 21 hours to process. Mr. Sim said the sterilizer doors automatically lock when high concentrations of EtO are measured in the chambers, and they cannot be opened manually. Mr. Sim said the sterilization chambers are temperature regulated by "jackets" used to heat or cool the chamber based on the stage of the cycle. Mr. Sim said the sterilizers complete seven air wash cycles using nitrogen after the sterilization process is complete.

Mr. Sim led the group to the hallway between primary aeration and secondary aeration.

Mr. Sim said a door opens from the back of the sterilizer and the product is mechanically moved from sterilization into primary aeration. Mr. Sim said product spends approximately 12 hours in primary aeration.

Mr. Sim said the secondary aeration product location and the duration it spends there depends on the product. Mr. Sim said "Suture Secondary Aeration" is used for suture products and can typically take 3 to 7 days. Mr. Sim said the "Suture Secondary Aeration" room can hold approximately 20 pallets of product. Mr. Sim said "Polymer Secondary Aeration" is used for polymer products and can typically take 48 to 50 hours, and a residual sample of EtO must be taken for product before it can be removed from aeration. Ms. Shea said the residual sample maximum EtO concentration is dependent on the product. Mr. Sim said "Polymer Secondary Aeration" room can hold approximately 20 pallets of product.

Ms. Shea led the group outside to the emissions control equipment. Ms. Shea said the EtO control system is a system manufactured by LENS I which includes a balancer and an oxidizer.

Ms. Shea said the balancer uses water to “hold” EtO and releases it to the oxidizer at a controlled rate. Ms. Shea said the rate that EtO is released is automated based on VOC measurement taken between the balancer and the oxidizer. Ms. Shea said the water flowing through the balancer and stripper column is a closed-loop system. Ms. Shea said the temperature of the water in the balancer is monitored. Ms. Shea said EtO concentration of the water in the balancer is not monitored. Mr. Sim said the amount of EtO entering the balancer is assumed to be equal to the amount of EtO loaded into the sterilizer.

Ms. Shea said a physical sample of the oxidizer catalyst bed is taken and analyzed annually by LENSI. Ms. Shea said the temperature at the outlet of the catalyst bed is recorded every 10 seconds and a daily average is calculated. Ms. Shea said the oxidizer has a manufacture recommended minimum temperature at the outlet from the catalyst bed of 150°F. Ms. Shea said the thermocouple is serviced every 6 months. Ms. Shea said EtO concentration is monitored after the catalyst however readings are not recorded.

Ms. Shea led the group to two Environmental Tectonics Corporation degassers. Ms. Shea said each degasser has a 6-pallet capacity. Ms. Shea said the degassers will be vented directly to the LENSI balancer/oxidizer control system.

Ms. Shea led the group to the gas chromatograph room. Ms. Patel documented gas chromatograph system information. Ms. Shea said the gas chromatograph has 16 sample points around the facility. Ms. Shea said a system calibration is completed twice a day with a 5ppm EtO calibration gas. Ms. Shea said monthly system calibrations are done using 2ppm EtO and 9ppm EtO calibration gases. Ms. Vasconcelos documented calibration gas information in Table 1. Ms. Shea said the gas chromatograph meets EPA PS9 standards.

Table 1: Gas Chromatograph Calibration Gases

Concentration (EtO)	Cylinder Number	Expiration Date
2ppm	ALM041363	4/7/2024
5ppm	CC483297	9/12/2023
9ppm	EB0115816	3/21/2024

Ms. Shea said Drager Polytrons gas monitoring devices are located around the facility as a secondary monitoring effort for EtO.

Ms. Shea led the group to the EtO storage room. Ms. Vasconcelos observed 6 EtO tanks, 4 of which were on top of digital scales. Mr. Sim said each tank can hold up to 400 lb of EtO. Ms. Vasconcelos documented the tare weight of each tank was 273 lb. Mr. Sim said the digital scales are calibrated every 6 months.

Ms. Shea led Ms. Vasconcelos, Ms. Patel, Mr. Ibrahim, Mr. Taborda, and Ms. Sullivan back to the conference room.

Records Reviewed:

Ms. Shea displayed the following records on the projector in the conference room:

- Gas chromatograph June 13, 2023, report demonstrating compliance with PS 9;
- Catalytic oxidizer bed sample report dated 6/5/2022 describing 6 samples taken and described “no signs of deactivation”, Ms. Sullivan said samples were taken 5/20/2022; and
- Catalytic oxidizer bed temperature monitoring spreadsheet for June 2023 showing raw recordings every 10 seconds and calculating daily averages.

Closing Conference:

Ms. Vasconcelos initiated a closing conference.

Ms. Sullivan said the capacity for the research and development chamber is 12 cu ft and uses approximately 0.2 to 0.6 lbs of EtO per cycle. Ms. Shea said there is a small EtO tank holding approximately 30 lbs of EtO located in the research and development room.

Ms. Shea said the total 2022 EtO usage for the facility had been 15,528 lb. Ms. Shea said the total 2022 EtO emission total had been 0.018 tons. Ms. Shea said the annual total for 2023 (January through June) is currently 8104.8 lbs. Ms. Shea said Covidien has a monitoring plan for the balancer, oxidizer, and gas chromatograph that describes operating parameters for each of the units.

Ms. Vasconcelos requested the following records be shared via email:

- Monitoring plans for the balancer, oxidizer, and gas chromatograph,
- Gas chromatograph report demonstrating compliance with PS9,
- List of gas chromatograph sampling points, and
- Copy of most recent stack test.

EPA representatives left the facility at 11:15am.