UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET SW
ATLANTA, GETORGIA 30303-8960

SENT VIA ELECTRONIC MAIL

Doug Parzuchowski
General Manager
International Sterilization Laboratory
217 Sampey Road
Groveland, Florida 34736
dparzuchowski@isl-fl.com

Dear Doug Parzuchowski:

On August 15, 2023, the U.S. Environmental Protection Agency Region 4 Air Enforcement Branch conducted a partial compliance inspection at International Sterilization Laboratory, located in Groveland, Florida. Enclosed is a copy of the final report generated by the U.S. Environmental Protection Agency's Region 4, South Air Enforcement Section.

Should you have questions regarding this inspection report, contact me at (404) 562-8837, or by email at Slade.Daniel@epa.gov.

Sincerely,

DANIEL SLADE Digitally signed by DANIEL SLADE
Date: 2023.09.20 11:19:20 -04'00'

Daniel Slade
Environmental Engineer
South Air Enforcement Section

CC: Jennifer Parker, Florida DEP
Talia Ayala, Florida DEP
Jeffery Koerner, Florida DEP

United States Environmental Protection Agency (EPA) Region 4
Air Enforcement Branch
Inspection Report

I. GENERAL INFORMATION

Facility Name: International Sterilization Laboratory

Location (Address): 217 Sampey Road Groveland, Florida 34736

Inspection Date: August 15, 2023

Type of Inspection (Full or Partial Compliance Evaluation):
Partial Compliance Evaluation

PROGRAMMATIC ID: FL0000001206904823

PERMIT NUMBER: Permit # 0694823-012-AO

EPA Region 4 Investigator(s)/Inspector(s):
1. Daniel Slade, Environmental Engineer
2. Steve Rieck, Environmental Scientist

State/Local Investigator(s)/Inspector(s):
1. Jennifer Parker, Florida DEP
2. Talia Ayala, Florida DEP
3. Jeffery Koerner, Florida DEP

Person(s) Contacted at Facility (Name and Title):
1. Doug Parzuchowski, General Manager

Report Prepared by: Daniel Slade

II. FACILITY INFORMATION

A. Facility and Permit Information

Facility and Permit Information	Comments
1. Type of facility (e.g., chemical plant, refinery, cement manufacturer, etc.).	Medical Device Sterilizer
2. Air permit number(s) and type of permit (e.g., Title V, PSD, Synthetic Minor, etc.).	Permit # 0694823-012-AO
3. Air permit issuance date.	December 22, 2020
4. Air permit expiration date.	December 22, 2025
5. Facility classification (Major, Synthetic Minor/Conditional Major, Minor).	Minor
6. Major source pollutants (if applicable).	Hazardous Air Pollutants (HAPs) – Ethylene Oxide
7. Applicable regulations (e.g., State Implementation Plan, MACT Subpart FFFF, NSPS Subpart EEEE, etc.).	40 C.F.R. Part 63, Subpart O - Ethylene Oxide Emissions Standards for Sterilization Facilities
8. Types of air emission points (e.g., tanks, process vents, boilers, etc.).	Sterilizer chambers and aeration room vents capture emissions and route to control equipment
9. Types of air pollution control equipment (e.g., baghouse, scrubber, afterburner, etc.).	Acid-water scrubbers

B. Process Description

International Sterilization Laboratory receives pre-packaged medical equipment from manufacturers. The medical equipment, already packaged and palletized, is pre-conditioned in an enclosed space to a specific temperature and humidity to improve sterilization efficiency.

Following pre-conditioning, equipment is loaded into one of four sterilization chambers. The chambers are sealed, a vacuum is drawn to remove the air in the chamber, and ethylene oxide (EtO) gas is injected. Residence time in the chamber is dependent upon customer specifications. After the residence time has been reached, the ETO is purged from the chamber and routed to

an acid-water scrubber. The chamber undergoes nitrogen and air purges to improve EtO removal.

Equipment is then taken to one of two aeration chambers. The facility operates one hot chamber (increased temperature and humidity) and one cold chamber (ambient air conditions). Equipment is kept in the chambers for approximately 24 hours to allow residual EtO to off-gas from material. The residual EtO is captured and routed to an acid-water scrubber. Equipment is moved to the facility's storage area until it is sent back to the customers.

III. INSPECTION ACTIVITIES

Activity	Yes No NA	Comments
Opening Meeting		
1. Date and time entered the facility.	Y	The EPA Region 4 inspection team and Florida DEP inspectors arrived at the facility on August 15, 2023, at 8:30 AM EDT.
2. Credentials presented to facility personnel (include name and title).	Y	Upon arrival, EPA inspectors presented credentials to Lori Zelenitz-Swisher, Quality Assurance Manager.
3. Conducted an opening meeting to explain the purpose and objectives of the inspection.	Y	The inspection team held an opening conference with Doug Parzuchowki, General Manager, to discuss inspection objectives.
4. Discussed safety issues.	Y	The inspection team discussed appropriate personal protective equipment prior to going to process areas.
5. Discussed which records to be reviewed.	Y	Facility staff provided the inspection team with records associated with Subpart O compliance. A list of documents reviewed can be found in Item 10 of this report.
6. Discussed the facility walk-through and the areas to be observed in the facility.	Y	The inspection team discussed the medical equipment sterilization process and facility process areas. All process areas of the facility were inspected during the walk-through.
7. Discussed facility policy regarding photographs or video (if applicable).	N/A	The inspection team notified facility staff when photographs were taken during the walk-through. All photographs are considered Confidential Business Information (CBI) until reviewed by facility staff.
8. Discussed the use of the infrared camera, TVA, PID, and any other equipment.	Y	The inspection team indicated that a FLIR camera and photoionization detector (PID) would be used during the process walkthrough.

Activity	Yes No NA	Comments
9. Discussed CBI.	Y	The inspection team indicated that any material claimed to be CBI would be treated in accordance with regulations.
Records Reviewed at the Facility		
10. The types of records reviewed, and the time period reviewed.	Y	The inspection team reviewed the following records on-site: **Records requested during the inspection:** 1. Acid-water scrubber operation and maintenance logs 2. Scrubber performance tests 3. EtO usage
Facility Walk-Through Observations		

Activity	Yes No NA	Comments
11. The process equipment observed and the associated operational rate observed (e.g., Furnace 1 production rate was 5 lbs/hr on 1/1/15, at 2:00 pm – permit requires max rate at 6 lbs/hr). Provide the date and time the information was recorded by the inspector. Identify the permit limit (if applicable). An attachment may be used for a large amount of information.	Y	Inspection of process areas began at 10:23 AM EDT. The inspection team observed the staging area for equipment. All equipment arrives to the facility pre-packaged. The equipment is kept on pallets and moved by forklift. The facility operates one large pre-conditioning room. The pre-conditioning process consists of raising heat and humidity of the equipment and does not have any associated emissions. Following pre-conditioning, the equipment is loaded into sterilization chambers. The facility operates four chambers all located in the same room. No emissions were detected by either the FLIR camera or PID. Following sterilization, the equipment is moved to one of two aeration rooms. One room is kept at ambient conditions (cold) and the other operates at an increased temperature and humidity (hot). The rooms are kept at these conditions to improve removal of residual EtO on equipment. Following aeration, the equipment is moved to a storage area and is picked up by the customer.

Activity	Yes No NA	Comments
12. The type of process parametric monitoring observed and the associated value observed (e.g., Furnace 1 flux injection rate was 200 lbs/batch at 1/1/15, at 2:00 pm – permit requires max rate at 225 lbs/batch). Provide the date and time the information was recorded by the inspector. Identify the permit limit (if applicable). An attachment may be used for a large amount of information.	N/A	
13. If process equipment or parametric monitoring equipment was not operating, state the reason by facility personnel why the equipment was not operating.	N/A	

Activity	Yes No NA	Comments
14. The type of air pollution control equipment, the process equipment it is controlling, and the associated parametric monitoring value observed (e.g., baghouse pressure drop, temperature, scrubber flow rate, etc.). (For example - RTO 1 controlling furnace 1, 1,500 degrees F on 1/1/15, at 2:00 pm – permit requires 1,400 degree F or higher). Provide the date and time the information was recorded by the inspector. Identify the permit limit (if applicable). An attachment may be used for a large amount of information.	Y	EtO sterilizer chamber and aeration room emissions are captured and routed to separate acid-water scrubbers. The scrubbers have a 99% destruction efficiency. Record review did not indicate any issues with scrubber operation.
15. Continuous emissions monitoring devices and values observed. (e.g., CEMS, COMs, etc.). Provide the date and time the information was recorded by the inspector. Identify the permit limit (if applicable). An attachment may be used for a large amount of information.	N/A	
16. If air pollution control equipment was not operating, state the reason by facility personnel why the equipment was not operating.	N/A	

Activity	Yes No NA	Comments
17. Capture and collection system (enclosures and hoods) observations, if applicable (e.g., the magnitude and duration of emission escaping capture from the hood).	N/A	
18. Ductwork transferring the emissions to the air pollution control device observations, if applicable (e.g., the magnitude and duration of emission escaping from the ductwork, holes or deterioration in ductwork, no deterioration observed, etc.).	N/A	
19. Any existing unpermitted emission points, new unpermitted emission points, or non-permitted construction activities observed. (if yes, describe in the comments field).	N	
20. Were any visible emissions observed? (if yes, identify the location and equipment).	N	No visible emissions were observed during the inspection.
21. Was a Method 9 reading performed? (if yes, identify the location and equipment).	N	
22. Was the cause of the visible emissions investigated and the information documented?	N	
23. Was a Method 22 performed for visible emissions? (if yes, identify the location and equipment).	N	
24. Identify the cause of the visible emissions as explained by facility personnel, if applicable.	N/A	

Activity	Yes No NA	Comments
25. Was the infrared camera used? If so, attach the video log (which includes the equipment ID, and the date and time the video was recorded) and videos to this report.	Y	No emissions were detected with the FLIR camera, and no videos were taken. The FLIR camera was used to take digital photos of process areas. More information can be found in Appendix A of this report.
26. Was the TVA used? If so, identify the equipment monitored and the results. Provide the date and time the information was recorded by the inspector. Include actual instrument readings for each piece of equipment monitored above the leak definition and/or where the infrared camera identified a release. An attachment may be used for a large amount of information.	N	
27. Was the PID used? If so, identify how the PID was used and the results. Provide the date and time the information was recorded by the inspector. An attachment may be used for a large amount of information.	Y	A PID was used at the facility during the walk-through. The PID was initially calibrated at 10:08 AM EDT following the opening meeting. During the walk-through, no spikes were noted from the PID in any of the process areas. Prior to leaving the facility, the PID was bump checked again at 11:10 AM EDT to ensure the initial calibration was still valid. The PID passed the bump check.
Closing Meeting		
28. Conducted a closing meeting.	Y	The Region 4 inspection team conducted a closing meeting on August 15, 2023, at 11:00 AM EDT with Mr. Parzuchowski.
29. Summarize any additional information needed, if applicable?	N/A	
30. Accept a declaration of CBI, if applicable?	N/A	Facility personnel did not declare or claim any documents as CBI, at the time of the inspection or during review of the draft inspection report.

Activity	Yes No NA	Comments
31. Discussed observations.	Y	The inspection team thanked facility staff for their time. The team discussed the facility walkthrough.
32. Discussed next steps, if applicable?	Y	A final inspection report from EPA Region 4 will be sent to the company within a 60-day timeframe.
33. Date and time inspection concluded.	Y	The inspection concluded on August 15, 2023, at 11:12 AM EDT.
Miscellaneous		
34. Include any additional observations, if applicable.	N/A	

EPA Investigator/Inspector Signature: DANIEL SLADE Digitally signed by DANIEL SLADE Date: 2023.09.20 11:20:08 -04'00'

EPA Supervisor Signature & Title: TODD GROENDYKE Digitally signed by TODD GROENDYKE Date: 2023.09.25 08:01:58 -04'00'

Chief, South Air Enforcement Section

Appendix A
Photograph log

During the August 15, 2023, inspection, EPA Region 4 staff used the FLIR GF320 camera to take digital photographs at International Sterilization Laboratory, located in Groveland, Florida. Below is an inventory of the images. All images were taken by EPA inspector Stephen Rieck. All times are in Eastern Daylight Time (EDT).

File Name	Time	Image Description
DC_0101	10:26 AM	Staging Area
DC_0102	10:26 AM	Sterilization Chambers
DC_0103	10:28 AM	Pre-conditioning Room
DC_0104	10:32 AM	Aeration Rooms
DC_0105	10:40 AM	EtO Storage Area
DC_0106	10:41 AM	Acid Water Scrubber