Region 2 Caribbean Environmental Protection Division
Multimedia Permits and Compliance Branch

CAA Inspection Report

Inspection Date: 12/4/2024

Facility Name: Steri-Tech Inc.

Facility Address: Road, 701, Km 0.7, Salinas Industrial Park, Salinas, Puerto Rico 00751

ICIS-Air ID #: PR0000007212300022

EPA Lead Inspector: Alex Rivera, Enforcement Officer, rivera.alex@epa.gov, 787-977-5845

EPA other attendees: Carlos Huertas-Hernández, On-Scene Coordinator, 787-977-5861

Eduardo A. Ortiz, On-Scene Coordinator, 787-977-5879

Facility Contact(s): Andrés Vivoni, VP & General Manager, 787-824-4040, avivoni@steri-tech.com

This report is a summary of observations and information gathered from the facility at the time of the inspection. The information provided does not constitute a final decision on compliance with Clean Air Act ("CAA") regulations or applicable permits, nor is it meant to be a comprehensive summary of all activities and processes conducted at the facility.

Summary of Onsite Observations

A. Opening Conference

Environmental Protection Agency (EPA) inspector Alex Rivera, and On-Scene Coordinators (OSCs) Carlos Huertas-Hernández and Eduardo A. Ortiz arrived at Steri-Tech Inc. ("Facility" or "STI") at approximately 3:30 pm. Inspector Rivera and OSCs Huertas and Ortiz presented credentials and identifications at the facility reception and were received by Mr. Giovanni Sánchez, Technical Services Manager. Mr. Sánchez escorted the EPA representatives to the Facility conference room. Ms. Melanie Rosado, EHS Specialist joined the inspection and Mr. Andres Vivoni, Vice President and General Manager joined via telephone. Inspector Rivera explained that the purpose of the inspection was to investigate an incident reported by a resident of the adjacent community about explosions and visible smoke and flame involving the facility thermal oxidizer (TO). The following is a summary of the topics discussed during the inspection opening conference:

1. Inspector Rivera showed a video provided by the community representative on which smoke and a visible flame can be seen from the facility thermal oxidizer.
2. Mr. Vivoni explained that on December 3, 2024, STI's propane supplying company was conducting a project to replace their current propane storage and supply system to increase the facility propane storage capacity. Mr. Vivoni added that as part of the activities the company replaced its propane storage tanks and supply piping, and that such actions required tests to be conducted which required

the TO to be on, but after the company completed the project, the STI personnel forgot to turn off the TO. Mr. Sánchez stated that the company completed the project around 3:00 PM.

3. Ms. Rosado explained that it was not until around 9:00 AM on December 4, 2024, that STI received a call from the PR Department of Natural and Environmental Resources (DNER) Air Quality Area, that STI became aware of the issue. Ms. Rosado stated that STI immediately turned the TO off and started investigating the issue.
4. Mr. Vivoni acknowledged that in addition to DNER's call, they received calls from several other agencies, including EPA and the FDA (U.S. Food and Drug Administration) to investigate the incident.
5. Mr. Vivoni explained that the TO was isolated from the sterilization process gas lines, and that the facility catalytic recuperative oxidizer (CRO) was in operation and controlling the facility EtO emissions.
6. Mr. Sánchez stated that the TO has an automatic set point of 1,500^{O}F, and explained that since the TO has been out of operation for a long period of time that could explained the smoke generation. Mr. Sanchez also mentioned that as part of STI's investigation of the issue, they inspected the unit and found pieces of carbonized refractory material at the bottom of the TO. Mr. Sánchez added that such condition could have caused by having the unit out of operation for a long period and the high temperatures kept throughout the night, and that could also explain the portion of the stack that can be seen red in the video provided by the community. Mr. Sanchez stated that if the stack is missing portions of its refractory material, it could create a condition like the one seen in the video.
7. Mr. Vivoni informed that he instructed his staff to physically disconnect the TO from its propane supply piping connection.
8. Mr. Vivoni indicated that both DNER and EPA will be receiving a written notification providing further details about the incident and STI's corrective actions.
9. Inspector Rivera requested to obtain copies of the TO temperature chart recorder. Mr. Vivoni indicated that since the TO has been out of operation, its chart recorder is offline and without paper, thus no chart is available to document the data from the period the unit was on. Mr. Vivoni added that the chart recorder was only used during the stack testing conducted in September 2024.
10. Mr. Vivoni informed that the propane storage increase project is part of the actions needed in preparation for the incorporation of the recently acquired LESNI® control device. Mr. Sánchez informed that the company that conducted the project is Light Gas Corporation, which is STI propane gas supplier, and that the project started on December 3, 2024, around 8:00 AM and was completed the same day around 3:00 PM.
11. Inspector Rivera requested copies of the CRO operational data and sterilization cycles system sheets completed from December 3-4, 2024. Mr. Vivoni instructed Ms. Rosado to provide copies of the requested information.
12. Inspector Rivera completed the opening conference meeting and requested to conduct a tour of the facility, specifically the area where the propane gas tanks and TO are located.

B. Facility Tour

At approximately 4:10 pm, Mr. Sánchez led Inspector Rivera, and OSCs Huertas and Ortiz on a tour of the Facility. Inspector Rivera informed that during the facility tour, they would capture digital images of the Facility, Mr. Sánchez agreed. The digital images taken during the inspection are included in Appendix A. The following is a summary of the observations made during the tour of the Facility:

1. Inspector Rivera asked Mr. Sánchez about how many operators were working on the night shift and that if they informed about any explosions. Mr. Sánchez informed that at least two operators worked during the night shift and that he has not been informed about any explosions.
2. Mr. Sánchez confirmed that pieces of carbonized refractory material were found at the bottom of the TO during the inspection conducted as part of STI incident investigation conducted earlier that day.

3. The facility previously has three (3) 500 gallons propane storage tanks. The project completed on December 3, 2024, consisted of the installation of three (3) new 1,000 gallons propane storage tanks and kept one (1) of the existing 500 gallons tanks. See Appendix A images PC040002 and PC040003 for further details.
4. Inspector Rivera asked Mr. Sánchez about the purpose of an enclosure material placed around the CRO. Mr. Sánchez informed that the enclosure material around the CRO was installed by STI to mitigate the noise that its operation generates.
5. The TO was off at the time of the inspection and Mr. Sánchez informed that a mechanic recently disconnected the TO from its propane supply piping. Mr. Sánchez showed Inspector Rivera where the disconnection was done and that the piping was blinded. See Appendix A image PC040004 and further details.
6. Inspector Rivera asked Mr. Sánchez about new piping connected to the CRO inlet. Mr. Sánchez informed that the piping is for the future connection of Chamber #6 and that the connection is currently blinded and disconnected. See Appendix A image PC040012 for further details.
7. Mr. Sánchez informed Inspector Rivera that STI also added a new connection next to the CRO fresh air damper that was for the purpose of adding air from the sterilization building as supplement to the fresh air intake, but the project is no longer under consideration. See Appendix A image PC040013 for further details.
8. Mr. Sánchez stated that night shift operators stay indoors and go outside if an alarm is triggered requiring an outdoor activity.
9. While returning to the administration area, Mr. Sánchez showed to Inspector Rivera several shipping containers located in an open lot across the street and north of the facility, and informed that the shipping containers are currently storing the LESNI® control device that was acquired as part of the necessary improvements to comply with the amendments of the NESHAP Subpart O[1].
10. Inspector Rivera asked Mr. Sánchez to provide access to the EtO indoor monitoring system control room. Mr. Sánchez provided access to the EtO indoor monitoring system control room and Inspector Rivera took a photo of the system monitor screen. See Appendix A image PC040015 for further details.
11. The tour was completed at approximately 4:40 PM.

C. Closing Meeting

Inspector Rivera proceeded with the inspection closing conference around 4:50 PM. Mr. Vivoni was not part of the closing conference. The following is a summary of closing conference discussion:

1. Ms. Rosado and Mr. Sánchez provided copies of the CRO operational data and sterilization cycles system sheets to Inspector Rivera.
2. Ms. Rosado explained that as indicated in the inspection opening meeting, the CRO operational data and sterilization cycles evidence that the CRO was in operation during December 3-4, 2024 and that ethylene oxide from the sterilization process was not being routed to the TO.
3. Ms. Rosado confirmed that two (2) sterilization cycles were active the night of December 3, 2024.
4. Mr. Sánchez confirmed that three (3) operators where working on December 3, 2024 second and third shifts.
5. Inspector Rivera asked Mr. Sánchez to confirm what type of sterilization activity was being performed at the time of the inspection. Mr. Sánchez confirmed that according to the sterilization supervisor, sterilization Chamber #4 was active, but completing its initial vacuum phase, as part of its conditioning phase.

[1] National Emission Standards for Hazardous Pollutants (NESHAP) Subpart O – Ethylene Oxide Emission Standards for Sterilization Facilities - https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O

6. Inspector Rivera asked Mr. Sánchez to explain how the alarm of the EtO indoor monitoring system works. Mr. Sánchez explained that the system has visual alarms and that when EtO concentrations at any of its 12 monitoring points exceed 5 ppm it will trigger a yellow-colored alarm and a red-colored alarmed when concentrations exceed 10 ppm. Mr. Sánchez added that occasional concentration spikes are showed in the system data and those are caused when operators open the sterilization chambers to remove the sterilized product and transfer it to the aeration rooms. Mr. Sánchez added, that prior to transferring the product to the aeration room, the operators remove the biological indicators that are placed at each batch, which is analyzed in a laboratory for confirming its subsequent release. Mr. Sánchez informed that operators are required to wear self-contained breathing apparatus while conducting the activity.

Inspector Rivera concluded the closing conference, thanked the facility for accommodating the inspection and left at approximately 5:30 pm. This concluded the inspection.

Appendices

A. Digital Image Log

End of Report

Lead Inspector's Name: Alex Rivera

ALEX RIVERA

Digitally signed by ALEX RIVERA
Date: 2024.12.10 11:20:05 -04'00'

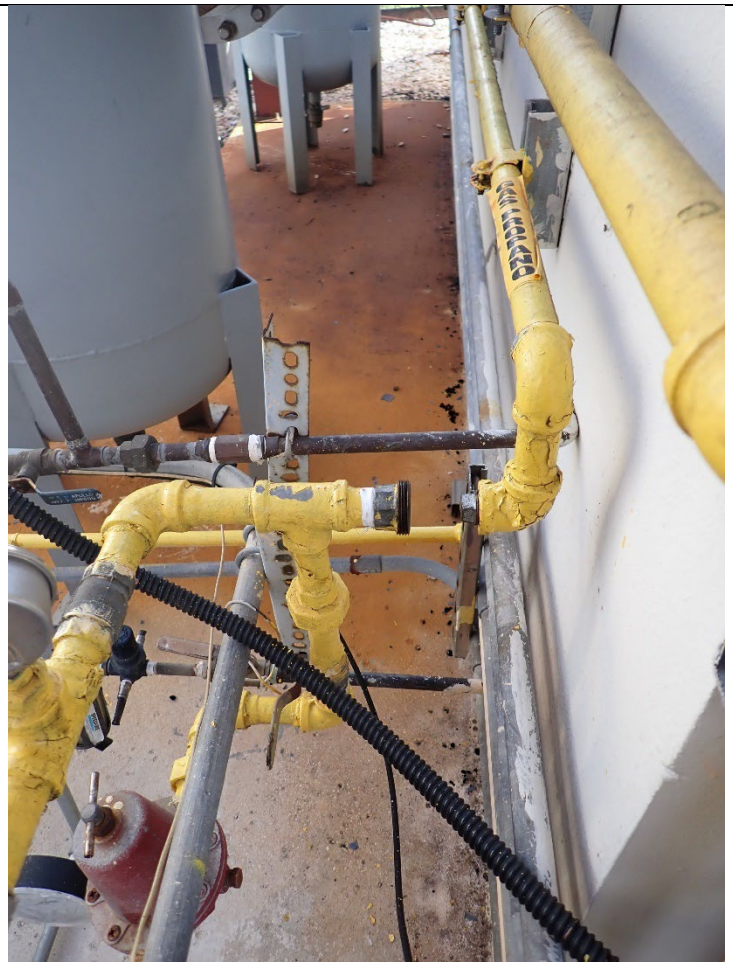
Supervisor's Name: Nancy Rodríguez

NANCY RODRIGUEZ

Digitally signed by NANCY RODRIGUEZ
Date: 2024.12.10 11:22:56 -04'00'

Appendix A: Digital Image Log for Steri-Tech Inc., Salinas, PR				
Facility Address: Road, 701, Km 0.7, Salinas Industrial Park, Salinas, Puerto Rico 00751		**Inspector:** Alex Rivera, EPA	**Image numbers:** PC040001 through PC040015 **Camera Used:** Olympus Tough TG-6 (EPA Decal # SM0134)	
File name: Appendix A Digital Image Log Steri-Tech Inc. 12-4-24				
Image Number	**File Name**	**Description**	**Date Taken**	**Time taken**
1	PC040001	 Partial view of the facility Catalytic Recuperative Oxidizer (CRO) and Thermal Oxidizer (TO)	12-4-24	16:13 PM

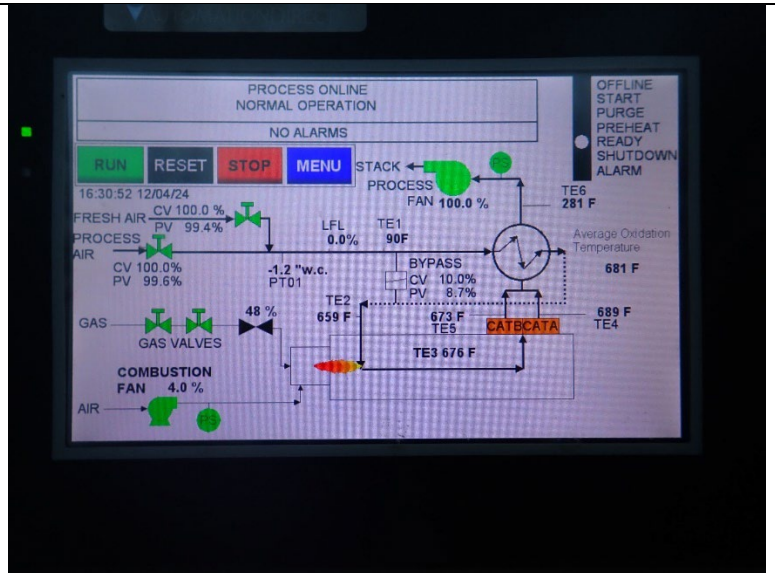
2	PC040002	 Partial view of the facility propane storage tanks.	12-4-24	16:16 PM
3	PC040003	 Partial view of the facility propane storage tanks.	12-4-24	16:16 PM

4	PC040004	 Partial view of the TO propane supply piping. The piping was cut and blinded at the time of the inspection to disconnect the TO from its propane supply.	12-4-24	16:20 PM

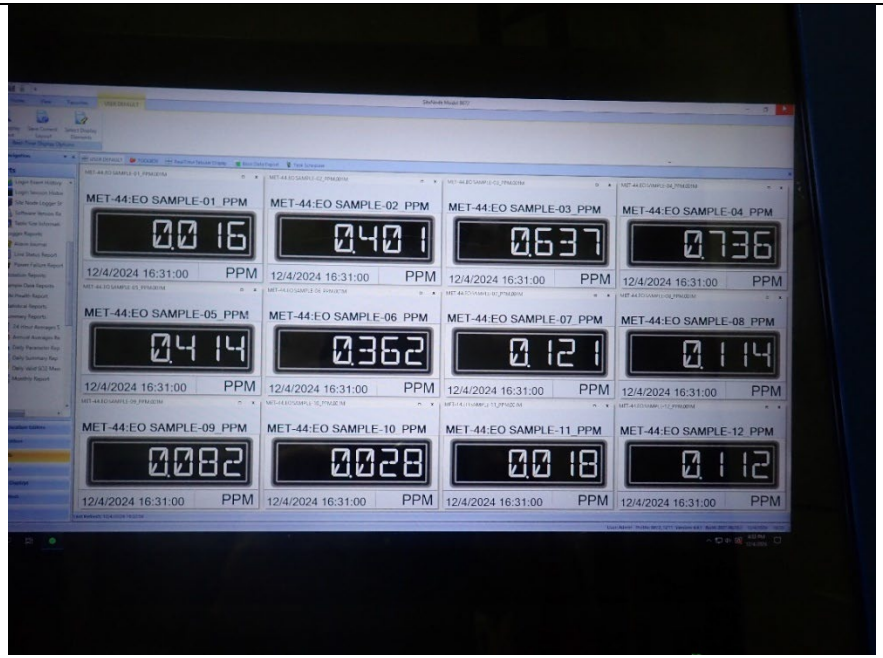
5	PC040005	 Partial view of the CRO and TO propane supply piping.	12-4-24	16:21 PM
6	PC040006	 Partial view of the facility aeration rooms and sterilization chambers process gas piping.	12-4-24	16:23 PM

7	PC040007	 Partial view of the facility aeration rooms and sterilization chambers process gas piping.	12-4-24	16:23 PM
8	PC040008	 Partial view of the facility aeration rooms and sterilization chambers process gas piping.	12-4-24	16:23 PM

9	PC040009	 Partial view of the facility aeration rooms and sterilization chambers process gas piping.	12-4-24	16:23 PM
10	PC040010	 Partial view of the facility aeration rooms and sterilization chambers process gas piping and its CRO and TO emission stacks.	12-4-24	16:23 PM

11	PC040011	 View of the CRO outdoor control panel screen.	12-4-24	16:25 PM
12	PC040012	 Partial view of the CRO process gas inlet pipe. A new inlet connection, currently blinded, was installed for allowing the future connection of Chamber 6.	12-4-24	16:27 PM

13	PC040013	 Partial view of the CRO fresh air damper.	12-4-24	16:30 PM
14	PC040014	 Partial view of the TO emission stack.	12-4-24	16:31 PM

15	PC040015	 View of the facility EtO indoor monitoring system control panel screen.	12-4-24	16:35 PM