UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, ILLINOIS 60604

SUBJECT:	CLEAN AIR ACT INSPECTION REPORT Midwest Sterilization Corporation, Laredo, Texas
FROM:	Jason Schenandoah, Environmental Engineer AECAB (IL/IN)
THRU:	Nathan Frank, Section Supervisor AECAB (IL/IN)
TO:	File

BASIC INFORMATION

Facility Name: Midwest Sterilization Corporation (MSC)

Facility Location: 12010 General Milton Dr, Laredo, Texas 78045

Date of Inspection: September 13, 2022

EPA Inspector(s):

1. Jason Schenandoah, Environmental Engineer
2. Daniel Heins, Environmental Scientist
3. Justin Chen, Environmental Engineer

Other Attendees:

1. Teodoro Soto, Plant Manager, MSC
2. Juan Martinez, Quality Assurance Manager, MSC
3. Edgar Hernandez, Maintenance Manager, MSC
4. Gerardo Garcia, General Manager, MSC
5. Eric Sisk, Director of Operations, MSC*
6. Karen Eldridge, CEO, MSC*
7. Michael Harrison, Corporate Project Manager, MSC*
8. Arnoldo Lanese, Section Manager, Texas Commission on Environmental Quality (TCEQ)
9. Evelyn Morales, Field Investigator, TCEQ
10. Brittany Chapa, Field Investigator, TCEQ

* Joined virtually for the closing conference only

Contact Email Address: gerardog@midweststerilization.com

Purpose of Inspection: To ensure compliance with the Clean Air Act

Facility Type: Medical equipment sterilization facility

Regulations Central to Inspection: 40 CFR Part 63 Subpart O - Ethylene Oxide Emissions Standards for Sterilization Facilities (Subpart O)

Arrival Time: 8:30 am
Departure Time: 2:45 pm

Inspection Type:
☒ Unannounced Inspection
☐ Announced Inspection

OPENING CONFERENCE

☒ Presented Credentials
☒ Stated authority and purpose of inspection
☐ Provided Small Business Resource Information Sheet
☒ Small Business Resource Information Sheet not provided. Reason: Not a small business
☒ Provided CBI warning to facility

EPA Region 5 inspectors Jason Schenandoah (J. Schenandoah), Daniel Heins (D. Heins), EPA Region 6 inspector Justin Chen (J. Chen), and TCEQ inspectors Arnaldo Lanese (A. Lanese), Evelyn Morales (E. Morales), and Brittany Chapa (B. Chapa) arrived at the Midwest Sterilization Corporation Laredo facility at 08:30 AM on September 13, 2022, for an unannounced inspection. Inspectors greeted Teodoro Soto/plant manager. J. Schenandoah, D Heins, and J. Chen presented credentials to Mr. Soto and informed him that this was an EPA inspection to determine compliance with the facility's Title V Air Permit and Subpart O. The scope of the inspection is a partial compliance evaluation specifically focusing on the lifecycle of ethylene oxide (EtO) from facility arrival to facility exit and investigation of potential fugitive emissions that might be unaccounted for or unauthorized. The inspectors informed Midwest Sterilization staff that they planned to inspect the facility and review documents related to the EtO sterilization process.

The following information was obtained verbally from MSC personnel unless otherwise noted.

Process Description:

Unsterilized equipment is received in boxes that are palletized. The pallets are broken down into smaller portions and inspected for potential damage, particularly looking for signs of moisture on the boxes. Product is counted and compared to manifests to verify the amount of product received. The product is then re-palletized and sent to one of 24 preconditioning rooms. The preconditioning rooms have temperature and humidity set for optimal bacterial growth. Optimal

bacterial growth conditions allow for any dormant bacteria to become active and ultimately make the bacteria more susceptible to the EtO sterilization process. The pallets of product will remain in a preconditioning room for 21 to 48 hours, depending on optimal timing by equipment type. When preconditioning is completed, product must be brought into one of ten sterilization chambers within 45-minutes to an hour. A software program is used to determine sterilization cycles specific to equipment type and customer needs. Before each sterilization cycle, a leak test is performed on the chamber as a vacuum is drawn on the chamber. Nitrogen and humidity are added to the chamber, per product requirements, before EtO is added for the dwell cycle. Each sterilization chamber has a dedicated station in the distribution room to service EtO to the chamber. EtO contained in drums is extracted from the drum by adding nitrogen to the drum to push the EtO out. It takes about 15 minutes for the required EtO to be injected into the chamber (typically 160-200 lbs.) after which the required pressure for the dwell cycle will be established. The chamber will circulate the gas in the chamber for two to seven hours throughout the dwell cycle. When the dwell cycle is complete, the gas is drawn out of the chamber. A series of gas washes are then initiated. The first gas wash is a nitrogen gas wash. A vacuum of 8-10 inches of mercury (" Hg), absolute is drawn on the chamber and then nitrogen is added until the chamber reaches 26" Hg absolute. The vacuum and nitrogen injection cycles back and forth 13-17 times depending on the product needs. The next gas wash is with air. Air is injected into the chamber until it reaches approximately 24" Hg absolute and then a vacuum is pulled on the chamber until it reaches 8-10" Hg absolute. The vacuum and air injection cycles back and forth 16-18 times. When the air wash is completed, the release phase is initiated. The chamber is first equalized with atmospheric pressure and then the chamber door is opened partially for 15-minutes to allow the gases in the chamber to flow into the back vent. The palletized product is then removed from the sterilization chamber and brought to one of 40 aeration rooms to be stored for 24 to 72 hours. In the aeration rooms, fresh air is cycled around the product to help remove residual EtO from the product and packaging. From the aeration room product is then stored in the warehouse portion of the Facility. Some product is staged for distribution and some product is picked up by the customer. The staged product will be distributed after the order is completed, while product picked up by the customer is typically done so within 24-36 hours.

After the first vacuum is drawn on the sterilization chambers before the dwell cycle, gases drawn from each chamber is sent to one of two scrubber towers (Scrubber 1 and Scrubber 2) in parallel and then sent through a third scrubber tower (Scrubber 3) that is in series with the first two scrubber towers. Chambers 1, 3, 5, 7, and 10 are directed to Scrubber 1 and chambers 2, 4, 6, 8, and 9 are directed to Scrubber 2. When the sterilization cycle is completed and the sterilization chamber door is opened, gases that are sent through the back vent are routed directly to Scrubber 3 from all chambers. Emissions from the aeration chambers are sent to one of 26 dry beds, called Safe Cells®, which consist of media that reacts with EtO for emissions control purposes.

Staff Interview:

A self-contained breathing apparatus is used by employees while retrieving products from the sterilization chambers and bringing them to the aeration chambers. For each scrubber, liquid flow and pH is monitored daily and glycol concentration is monitored weekly. If the pH of a scrubber is too high, sulfuric acid is added to the system. If glycol concentration is too high, glycol is removed from the system and fresh water is added. Wastewater is shipped to a disposal company. If liquid flow is too low, an alarm is activated and a backup pump will be turned on

manually to ensure that adequate flow is maintained in the scrubber. Scrubber 3 was installed and put into use in December 2021. Under direction of and reported to TCEQ, a stack test was performed after Scrubber 3's installation to determine total control efficiency for the scrubber system. The stack test included 3 separate tests. The first two tests each had four sterilization chambers conducting a sterilization process congruently and routing to Scrubbers 1 and 3 in series and Scrubbers 2 and 3 in series, respectively. A third test was conducted to have 4 chambers in the release phase and routing back vent emissions directly to Scrubber 3. A gas chromatograph (GC) is used to measure the inlet and outlet of each of the Safe Cells® once per day and recorded once per month. If the EtO concentration of 0.6 parts per million (ppm) is measured at the outlet of any of the Safe Cells®, the media is replaced following the measurement. Media in the Safe Cells® are regularly mixed to avoid channeling. At the time of inspection there was a current project underway to add an additional eight Safe Cells®. A measurement is taken at the exhaust stack with the GC once per day and recorded once per month. While touring the room containing the GC, a reading of 0.5 ppm at the stack was measured. In addition to the leak tests that are part of the sterilization process, maintenance will spray equipment with soapy water to check for leaks. Leak tests are also performed any time a new piece of equipment is replaced on the sterilization chambers. Inspections are performed on the sterilization chambers and associated piping every three years according to American Petroleum Institute (API) standards.

TOUR INFORMATION

EPA Tour of the Facility: Yes

Data Collected and Observations:

During the inspection, EPA inspectors and MSC personnel toured the Facility in the following order:

1. EtO storage room
2. EtO distribution room
3. Sterilization chamber 2 and 3
4. Scrubbers 1 and 2
5. Safe Cells® building
6. Scrubber 3
7. Sterilization chamber 2
8. Sterilization chamber 9
9. Aeration chamber 35

The sterilization chambers are located in bays that are connected to a hall-like common room and the aeration rooms open up to the hall-like common room as well. An assessment for exhausting the ambient air in the hall-like common room to a new control device is being considered by MSC.

Photos and/or Videos: were taken during the inspection.

Optical Gas Imaging (OGI) was conducted using a Forward Looking Infrared (FLIR) camera during the inspection. EPA witnessed sterilization chamber 3 throughout the release phase. MSC operators opened the sterilization chamber door all the way and EPA inspectors performed OGI as that process occurred. No gases could be visualized while performing OGI on sterilization chamber 3. EPA also performed OGI as aeration chamber 35 was opened after an aeration process was completed. No gases could be visualized while performing OGI on aeration chamber 35 as it was opened. Photos and FLIR video are logged in Appendix A: Digital Image Log

Field Measurements: were taken during this inspection.

EPA inspectors utilized two Toxic Vapor Analyzer (TVA) 2020s to conduct EPA Method 21 (Method 21) measurements on equipment in EtO service at the EtO storage room and EtO distribution room. Recorded measurements in the EtO storage room and EtO distribution room are detailed in Appendix B: Field Measurement Data. Applicable regulations do not require Method 21 monitoring or tagging of equipment for the purposes of fugitive leak detection in the EtO storage room and EtO distribution room. Since no tags are used on the equipment for identification, all measurements made were communicated to MSC personnel while monitoring occurred. Method 21 was also conducted on equipment associated with sterilization chambers 2 and 9. EPA inspectors ascended to the top of sterilization chamber 2 prior to EtO injection and a background measurement of 1 ppm was displayed on the TVA in use. During the EtO injection process, the background measurement increased to 2.5 ppm. While performing Method 21, no piece of equipment on sterilization chamber 2 measured above background. After the dwell cycle started on sterilization chamber 2, there was not a significant difference between the background in the hall-like common room and sterilization chamber 3's bay area. Sterilization chamber 9 was in the dwell cycle while Method 21 was performed on the chamber's equipment. No measurements above background were noted while conducting Method 21 on sterilization chamber 9. TVAs were also utilized to measure ambient air in the hall-like common room while aeration chamber 35 was opened. Background was measured at approximately 1 ppm before the door was opened and after the door was opened ambient measurements increased to about 3 ppm. Method 21 measurements were conducted around the periphery of the palletized boxes. On the side of the cardboard, where the corrugation is exposed, readings between 10 – 78 ppm were measured.

RECORDS REVIEW

1. Map overview of MSC facility
2. Weekly preventative maintenance report for week of September 5, 2022
3. Monthly scrubber parameter monitoring log for August 2022

CLOSING CONFERENCE

☒ Provided U.S. EPA point of contact to the facility

Requested documents:

- 2021 scrubber stack test report
- Last API piping inspection report

- Last API pressure vessel inspection report
- Safety Data Sheet for media used in Safe Cells®

Compliance Assistance: MSC personnel inquired about the use of TVAs to conduct Method 21. EPA inspectors recommended that Method 21 be conducted on the sterilization chambers while active injection is occurring.

Next Steps: There are no further questions regarding the scope of this inspection.

DIGITAL SIGNATURES

Report Author: JASON SCHENANDOAH Digitally signed by JASON SCHENANDOAH Date: 2022.11.10 09:25:52 -06'00'

Section Supervisor: Frank, Nathan Digitally signed by Frank, Nathan Date: 2022.11.14 13:19:35 -06'00'

APPENDICES AND ATTACHMENTS

1. Appendix A: Digital Image Log
2. Appendix B: Field Measurement Data

Facility Name: Midwest Sterilization Corporation
Facility Location: 12010 General Milton Dr, Laredo, Texas 78045
Date of Inspection: September 13, 2022

APPENDIX A: DIGITAL IMAGE LOG

1. **Inspector Name:** Justin Chen	2. **Archival Record Location:** Region 5 Electronic Records Center; Case name: Enf_MidwestSterilization_TX_22

Image Number	File Name	Date and Time (incl. Time zone and DST)	Description of Image
1	DSCN1035.JPG	2022:09:13 10:34:54 AM	EtO storage room
2	DSCN1036.JPG	2022:09:13 10:36:48 AM	EtO distribution room
3	DSCN1037.JPG	2022:09:13 10:47:15 AM	Sterilization Chamber 2
4	DSCN1038.JPG	2022:09:13 11:01:20 AM	EtO distribution piping from vessel for sterilization chamber 1
5	DSCN1039.JPG	2022:09:13 11:49:36 AM	Wet scrubbers 1 and 2
6	DSCN1040.JPG	2022:09:13 11:52:21 AM	Wet scrubbers 1 and 2 tanks
7	DSCN1041.JPG	2022:09:13 11:57:10 AM	Safe Cells control room
8	DSCN1042.JPG	2022:09:13 12:02:25 AM	Scrubber 3 and water tanks
9	MOV_0077.mp4	2022:09:13 11:30 AM	Opening of sterilization chamber 3
10	MOV_0078.mp4	2022:09:13 11:45 AM	Opening of aeration room 35

APPENDIX B: FIELD MEASUREMENT DATA

- EPA used two TVA 2020 models to conduct comparative Method 21 monitoring.
- EPA calibrated TVAs #SL1555 and #B37055 before use with the following calibrations gas standards: Zero Air, 500 ppm as Methane, and 10,000 ppm as Methane.

9/13/2022 Initial Calibration		
Span Gas (ppm)	EPA # SL1555	EPA # B37055
500	497	496
10000	10,000	9,937

Date	Equipment	Equipment Type	Reading	TVA ID#
9/13/2022	Empty EtO drum	valve	4 ppm	B37055
9/13/2022	Distribution Vessel # 1	Valve	4.5 ppm	B37055
9/13/2022	Distribution Vessel # 2	Valve	8.4 ppm	B37055
9/13/2022	Distribution Vessel # 1	Flange	28 ppm	B37055
9/13/2022	Distribution Vessel # 7	Valve	12 ppm	SL1555