UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1
5 POST OFFICE SQUARE, SUITE 100
BOSTON, MASSACHUSETTS 02109-3912

Clean Air Act Inspection Report

Drafted: September 12, 2022
Finalized: September 21, 2022

EPA Inspector: Darren Fortescue, Senior Enforcement Coordinator, Air Compliance Section /DEF/

EPA Reviewer: Elizabeth Kudarauskas, Acting Manager, Air Compliance Section /EAK/

Date of Inspection: August 30, 2022

Facility Name: Isomedix Operations, Inc. a Steris Applied Sterilization Technologies Company

ICISAir ID#: MA0000002511800041

Facility Location: 435 Whitney Street, Northborough, MA 01532

Mailing Address: 5960 Heisley Road, Mentor, OH 44060

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
Darren Fortescue	Senior Enforcement Coordinator	EPA Region 1
Tyler Kotsifas	Environmental Scientist	EPA Region 1
Randa Kallin	Environmental Analyst	Mass DEP
Maria L'Annunziata	Environmental Analyst	Mass DEP
Michael Carelli	Plant Manager	Steris
Joseph Remuck	Maintenance Manager	Steris

Facility/Process Description:

History

The facility, located at 435 Whitney Street, Northborough, Massachusetts, is owned and operated by Isomedix Operations, Inc. a Steris Applied Sterilization Technologies Company ("Steris"). The facility was originally owned by Isomedix Operations, Inc ("Isomedix") and in 1997-98 Isomedix was purchased by Steris. The facility is a contract sterilization facility and provides gamma irradiation and ethylene oxide ("EtO") sterilization services. Steris sterilizes a variety of devices including, but not necessarily limited to, medical devices.

The facility was built in 1982 and, at that time, only offered gamma irradiation services. In 1992 the facility footprint was expanded from 30,000 ft^3 to 55,000 ft^3, and EtO sterilization services were added.

Gamma Irradiation Sterilization

The facility operates a batch gamma irradiation sterilization process. Nine individual carriers are used that mechanically feed through a gamma irradiation area.

Pallets of products are broken down on the receiving side of the warehouse and the products are loaded into the carriers. The carriers are mechanically fed into the gamma irradiation area where they are rotated around several gamma radiation sources. The carriers undergo a timed dwell in the sterilization area before returning to the production side of the warehouse, where the products are unpacked from the carriers and reloaded onto pallets.

EtO Sterilization and Aeration

Steris has four ETC Sterilization Systems, 2,100 ft^3, EtO sterilization chambers installed at the facility. The facility also has four primary aeration rooms and one common secondary aeration room.

Products requiring EtO sterilization remain packed on pallets. The pallets are moved into a pre-conditioning room maintained at 113°F and 65% humidity. The pallets are pre-conditioned for a time period of between 11 and 40 hours.

After pre-conditioning, the pallets are forklifted onto conveyor belts and fed into the sterilization chambers. The pallets of products undergo a sterilization cycle consisting of an initial evacuation and leak test, followed by a nitrogen dilution and a humidity phase, then EtO is introduced to the chamber for a dwell time of approximately 4 hours. The chambers then undergo a series of nitrogen washes and, occasionally, air washes.

After the sterilization cycle is complete, conveyor belts move the pallets out of the chambers and into one of the four primary aeration rooms, where they undergo an aeration dwell of between six hours to 25 days (majority undergo a two-to-three-day aeration dwell). The primary aeration rooms are maintained at 113ºF at low humidity.

After primary aeration the pallets are moved by forklift to secondary aeration and then into the production side of the warehouse.

EtO Pollution Control Systems

EtO sterilization chamber vent emissions are ducted to an Anguil Environmental Systems, Model 20, absorption desorption unit, commonly referred to as a peak shaver. The system consists of a packed tower that uses water as a scrubbing medium, a 10,000-gallon storage tank and associated fans, pumps and piping. The unit accepts and absorbs EtO in spikes from the sterilization chambers and then desorbs EtO at a constant rate for control.

Flue gas from the peak shaver is combined with emissions from both primary and secondary aeration, and they are ducted to a Donaldson catalytic thermal oxidizer, commonly referred to as an abator. The abator uses natural gas as a fuel and has a design capacity of 20,000 scfm.

Steris recently installed Safe Cell Bed Media systems to capture and control fugitive emissions from the EtO drum room and the process warehouse.

EtO Monitoring

Steris has a gas chromatograph air monitoring system in place to monitor room concentrations of EtO.

Number of Employees and Working Hours:

Steris employs 55 people at the facility. The facility operates 24 hours per a day, 363 days per year.

Potentially Applicable Clean Air Act Requirements:

- 40 CFR Part 63, Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities ("Subpart O").
- Mass DEP Limited Plan Approval No. W058285

Previous Enforcement Actions:

A "Detailed Facility Report" from EPA's Enforcement and Compliance History Online database indicates that on March 4, 2021, Mass DEP issued the facility a notice of non-compliance.

Opening Conference:

Entry

On August 30, 2022, at 09:00 am, EPA Region 1 representatives Darren Fortescue and Tyler Kotsifas, and Mass DEP representatives Randa Kallin and Maria L'Annunziata arrived at the Steris facility, located at 435 Whitney Street, Northborough, Massachusetts and met Michael Carelli and Joseph Remuck of Steris. Mr. Fortescue presented his credentials and initiated an opening conference.

Conference

Facility representatives said that the four exiting EtO sterilization chambers were installed in 1992 and no significant changes have been made to the sterilization process since then. Facility representatives said the original control device used to control sterilization chamber vent emissions had been a flare; however, in 2005 it was identified that the flare did not meet the required removal efficiency, so in the 2006 to 2008 timeframe the pollution control system was upgraded to the current configuration.

Facility representatives said the facility uses approximately 330,000 pounds of EtO annually.

Facility representatives said that Steris is proactively preparing for any future changes to Subpart O requirements. Facility representatives said Steris has installed Safe Cell Bed Media systems to control fugitive room emissions at the facility and did so prior to any regulatory requirement for this kind of capture and control. Facility representatives said that Steris is also implementing an EtO sustainability program aimed at reviewing and modifying processes at the facility to reduce EtO usage.

Facility representatives said the date of the last Subpart O performance test was August 1, 2006. Facility representatives provided an executive summary of the 2006 performance test for EPA representatives to review. Facility representatives said they would be able to provide the full performance test report by email.

Facility representatives said that Steris changes out the abator catalyst every five years and the last replacement occurred the summer of 2021.

Facility representatives said that the catalyst bed temperature of the abator is monitored and maintained at or above 280 ^{o}F. Facility representatives said they are not sure if the temperature operating limit is based on a manufacturer's recommendation.

Facility representatives said that the monitoring parameters for the peak shaver are:

- Water flow;
- Water level;
- If the abator is running;
- Stack pressures; and
- Tank water temperature.

Facility representatives said that the water nozzles and rupture disks are checked twice per year.

Mr. Fortescue asked if Steris had engaged with EPA to receive approval of the peak shaver monitoring parameters and facility representatives said they are not sure if this had happened. Facility representatives said that the limits for the peak shaver monitoring parameters that are described in the Mass DEP Air Permit (Mass DEP Limited Plan Approval No. W058285) may be based on manufacturer's recommendations.

Facility representatives said they are not sure if peak shaver operating data are included in the performance test report for testing conducted in 2006.

Facility representatives showed inspectors an electronic copy of a letter that was sent to Mass DEP in the 2006 timeframe. The letter described the installation of the peak shaver. Facility representatives said they could provide a copy of the letter to the inspectors via email.

Facility representatives said they are not sure if an updated Notification of Compliance Status ("NOCS") had been submitted to EPA when the 2006 performance testing was conducted.

Facility representatives said that reactivity testing of the abator catalyst had been planned but not conducted.

Prior to a facility walk through, the group viewed a safety video.

Facility Tour:

The group proceeded on a tour of the facility.

Initially the group entered a warehouse that Mr. Carelli said is the receiving warehouse. Mr. Carelli pointed out several metal containers that were suspended from an overhead conveyor

system and said they are the product carriers for the gamma irradiation process. Mr. Carelli pointed out a large orange door and said it is the entrance to the gamma irradiation area. Mr. Fortescue observed that the overhead conveyor system appeared to be configured to allow the carriers to be fed into and out of the irradiation area behind the orange door.

Mr. Carelli said the irradiation area has 24 gamma producing slugs of Cobalt 60 material that are stored in water. Mr. Carelli said when the carriers are fed into the irradiation area, the slugs are raised out of the water and the carriers are rotated around the slugs to achieve a consistent dwell time for all the products in the carriers.

The group proceeded to a control room that Mr. Carelli said was the EtO control room. Mr. Fortescue observed four chamber displays that were displaying environmental conditions in the sterilization chambers. Mr. Fortescue observed that a separate display indicated that the abator was running and the catalyst bed temperature was 325 ^{o}F. Facility representatives said that the peak shaver monitoring is performed and recorded in the peak shaver room.

The group proceeded to a large room that Mr. Carrelli described as the pre-conditioning room. Mr. Fortescue noted the atmosphere in the room was very hot and humid. Mr. Fortescue observed four conveyor systems leading up to doors. Mr. Carelli said that after pallets of products are preconditioned, they are placed on the conveyors and fed into the sterilization chambers. Facility representatives opened a door to one of the empty sterilization chambers to allow the group to see inside.

Facility representatives said that two process boilers are operated at the facility and are run on natural gas.

The group proceeded to the roof of the main building. Mr. Carelli pointed out a control device and said it was the abator. Mr. Fortescue and Mr. Kotsifas observed that a meter on the control device appeared to display a temperature reading of approximately 350^{o}F; however, they observed that the meter had moisture in it making it difficult to get an accurate reading.

The group proceeded to the EtO drum room. Mr. Carelli said a negative pressure pulls liquid EtO out of the drums and a liquid vaporizer system converts the EtO to gas for use in the sterilization chambers. Mr. Carelli said the facility uses the pressure differential in the chambers to determine the quantity of EtO used; however, he said they also use scales to crosscheck the data. Mr. Carelli said that pressure transducers have performance evaluations conducted on them four times a year.

The group proceeded to a building that Facility representatives said houses the peak shaver. Facility representatives said the peak shaver has nozzles for water spray and a packing material over a water reservoir. Mr. Fortescue documented that a control panel indicated the differential

pressure was 5.688 inches of water, the water flow was 252.87 gallons per minute, the water temperature was 20.08 ^{o}F, the water level was at 39.71% and the high pressure was 16.080 inches of water. Mr. Fortescue documented that the high pressure reading on the control panel was intermittently changing from a numerical reading to arrows pointing upward.

Closing Conference:

Mr. Fortescue thanked facility representatives for their time.

Mr. Fortescue confirmed that facility representatives would provide copies of the 2006 performance test report, the 2006 NOCS, and the letter Steris had sent to Mass DEP in approximately 2006 describing the peak shaver control device.

Mr. Fortescue asked that Steris attempt to investigate whether EPA had been involved in the process of establishing operating parameters and limits for the peak shaver when it was installed. Facility representatives said they would let EPA know if they were able to determine that this had happened.