



United States Environmental Protection Agency
Region 7
Enforcement and Compliance Assurance Division

Air Branch

Air Branch Inspection Report
Unannounced Full Compliance Evaluation
American Contract Systems, Inc.
1601 SE Gateway Drive, Suite 120
Grimes, Iowa 50111
FRS# : 110031468329

Inspection Date:
December 19, 2023

Christopher Appier, Inspector, ECAD, Air Branch

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INSPECTION OVERVIEW

INSPECTION OBJECTIVE

The objective of the full compliance evaluation (FCE) inspection was to determine compliance of the facility with the Clean Air Act (CAA), specifically those requirements located in the Code of Federal Regulations at 40 CFR Part 63, Subpart O, Ethylene Oxide Emissions Standards for Sterilization Facilities (Maximum Achievable Control Technology (MACT) O) and in the Construction Permit (Permit Number 1982 Modified #4 AIRC-2021-48134) issued by the Polk County Air Quality Division on August 12, 2021 (the construction permit). This report documents EPA's activities on site.

Table 1 lists the inspection team members.

Table 1. PROJECT TEAM MEMBERS		
Team Member	Organization	Project Role
Christopher Appier	EPA Region 7, ECAD, Air Branch	Lead Inspector
Hunter Strom	EPA Region 7, ECAD, Air Branch	Field team member

FACILITY CONTACT INFORMATION

Table 2 lists the primary facility contacts.

Table 2. FACILITY CONTACT INFORMATION		
Name, Title	Phone No.	Email Address
Jeramie McElderry	(515) 253-8463	Jeramie.McElderry@owens-minor.com
William Swanger, Director, Environmental, Health, and Safety	(480) 645-2430	William.Swanger@hyh.com
Jeremy Upenieks		-
Philip Fleischhacker, Sr. Engineer and Technical Manager		Philip.Fleischhacker@owens-minor.com

FACILITY OVERVIEW

American Contract Systems, Inc. (ACS) uses ethylene oxide (EtO), a hazardous air pollutant listed in Section 112 of the CAA, to sterilize medical equipment that cannot be suitably sterilized using steam. ACS uses a single item sterilization process, which is carried out in four primary areas: the Breakdown and Assembly Room, the Injection Room, the Aeration Room, and EtO Storage Room. The facility has been at its current location since 2016 and has 39 employees. The facility operates from 5:00 a.m. to 5:30 p.m., Monday through Friday.

MACT O applies to commercial sterilization and fumigation sources that use EtO as a sterilant, regardless of the EtO usage amount. However, the rule does have varying requirements that

depend on the 12-month rolling average EtO usage of the facility. ACS falls into the Source Type of ≥ 1 ton and < 10 tons of 12-month rolling average EtO usage.

The requirements from the permit and MACT O listed below are relevant to the observations made during this inspection.

Section 63.361 defines a sterilization chamber as “any enclosed vessel or room that is filled with ethylene oxide gas, or an ethylene oxide/inert gas mixture, for the purpose of sterilizing and/or fumigating at a sterilization facility.”

Section 63.361 defines a sterilization chamber vent as “the point (prior to the vacuum pump) through which the evacuation of ethylene oxide from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.”

Table 3 lists the applicable emission standards.

TABLE 3. Section 63.362 EMISSION STANDARDS FOR ETO COMMERCIAL STERILIZERS			
Source Type	Sterilization Chamber Vent	Aeration Room Vent	Chamber Exhaust Vent
< 907 kg (1 ton)	No control required		
≥ 907 kg (1 ton) And $< 9,070$ kg (10 tons)	99% emission reduction	No control required	
$> 9,070$ kg (10 tons)	99% emission reduction	1 part per million (ppm) max outlet concentration or 99% emission reduction	No control required

Section 63.360(g)(2) states that “The owner or operating shall comply with the provisions of this subpart as follows: All sterilization chamber vents subject to the emission standards in § 63.362 with an initial startup date on or after December 6, 1998, immediately upon initial startup of the source.”

Section 63.363(a)(2) states that “The owner or operator of all sources subject to these emissions standards shall complete the performance test within 180 days after the compliance date for the specific source as determined in § 63.360(g).”

Section 63.363(e) requires that facilities complying with emission limits under § 63.362 with a control technology other than acid-water scrubbers or catalytic or thermal oxidizers provide to the Administrator or delegated authority information describing the design and operation of the air pollution control system, including recommendations for the operating parameters to be monitored to demonstrate continuous compliance.

Section 12 of the construction permit (**Appendix A**) lists Additional Limits which require that the facility, on a monthly basis, record the amount of EtO used and calculate a 12-month rolling total. It also states that “these records shall be kept on site for a minimum period of five years.”

Section 12 of the construction permit lists Additional Limits which require that “the owner or operator shall follow the compliance plan submitted to Polk County on January 14, 2021 to demonstrate compliance per § 63.363(e). The compliance plan includes... Each Magnehelic gauge will be monitored daily and documented weekly.”

FACILITY OPERATIONS SUMMARY

The sterilization process consists of the following generalized steps. First, unsterilized medical equipment and EtO containers are delivered to ACS. The EtO is stored in a cabinet in the EtO Storage Room. This cabinet can be seen in Image IMG_0124.JPG(**Appendix B**). The medical equipment is placed inside semi-permeable sterilization bags in the Breakdown and Assembly Room. These bags are then taken to the Injection Room where they are filled with EtO using an in-house designed A-BIO-VAC unit. After injection, the bags are placed into cardboard boxes, which are stacked on pallets held under a ventilated hood during loading. Once a pallet is fully loaded, it is placed in an aeration chamber in the Aeration Room. Image IMG_0126.JPG shows the outside of an aeration chamber and Image IMG_0125.JPG shows the inside of a chamber filled with product. The aeration chambers, of which there are 12, are humidity and temperature controlled to optimize sterilization efficacy. The bags are kept in the aeration chambers for 64 hours. The EtO slowly permeates out of the bags during this period. The aeration chambers are maintained under negative pressure and the emissions exhausted. The emissions are routed through dry-bed scrubbers equipped with differential pressure gauges. Each of the four scrubbers controls the emissions from three aeration chambers. The scrubbers and their pressure gauges can be seen in Images IMG_0127.JPG – IMG_0129.JPG. After removal from the aeration chamber, the items are stored until ready to ship.

FIELD ACTIVITIES SUMMARY

Mr. Strom and I arrived at the facility on December 19, 2023, at 9:00 a.m. and completed a drive-by surveillance inspection. I did not observe visible emissions. I made entry at the front door and introduced myself and members of the inspection team and presented my credentials to Mr. Jeremy Upeneiks at 09:05 a.m. I conducted an opening conference during which I explained that the purpose of the visit was to conduct an inspection to determine compliance with the CAA, specifically, to determine compliance with the regulations and standards listed in MACT O and the construction permit. I explained that after asking for some general business information, I would observe work practices, process units, emission units, and control equipment and review associated records demonstrating compliance with MACT O and the construction permit.

The first portion of the facility tour was given by Mr. Upeneiks, during which he explained the details of the facility operations. During the facility tour, Mr. Strom conducted sampling using a PpbRae handheld volatile organic compound (VOC) monitor. For more information on this sampling, see the Measurement Activities and Investigation Observations and Potential Findings sections below. Mr. Strom and I wore a hair net and surgical gown at the request of Mr. Upeneiks. We first observed the shipping area where shipments of EtO and medical equipment are brought into the facility. Next, we observed the storage room where the new and used containers of EtO are kept while not in use. After the storage room, we viewed the injection room. At this point, Mr. Jeramie McElderry conducted the facility tour. Last, we observed the aeration chambers and the scrubbers used to control their emissions.

After the facility tour, I met with Mr. McElderry in a conference room and requested several documents to demonstrate compliance with MACT O and the construction permit. Mr. McElderry was able to provide me with three years of EtO usage records (claimed as confidential business information). Mr. McElderry suggested that I should contact Mr. William Swanger, the Director of Environmental, Health, and Safety, for the remainder of the documents I requested. Mr. Swanger provided me with a stack test report for the scrubbers from April 21-22, 2022 (**Appendix C**), an SDS sheet for the scrubber media, the operating and maintenance manual for the scrubbers (**Appendix D**), a principle of operation sheet for the scrubbers, and a copy of the compliance sheet he used to track the scrubber media changes (**Appendix E**) via email.

I conducted a closing conference with Mr. McElderry. I explained to Mr. McElderry that the facility could make a claim of business confidentiality. Mr. McElderry did make a claim of confidentiality for the EtO usage records. I provided him with copies of the confidential business information form (**Appendix F**), a receipt for documents (**Appendix G**), and a small business information sheet.

Observations and potential findings from the facility tour, and records review, and sampling activities are noted in the **Investigation Observation and Potential Findings** section below.

Measurement Activities

Mr. Strom conducted sampling during the onsite inspection under my direction. Sampling was conducted throughout the entire facility tour portion of the inspection. **Table 4** summarizes field measurement and field sampling activities.

The PpbRae was equipped with a 10.6 eV bulb and was calibrated using isobutylene. According to Honeywell, the response factor for EtO is 13. **Appendix H** contains a guideline for PID instrument response produced by Honeywell, the manufacturer of the PpbRae.

All environmental measurement activities were performed in accordance with the EPA Region 7 quality system. Mr. Strom and I followed manufacturer and EPA processes for instrument calibration; instrument calibration was documented in the field notebook accompanying the ppbRae. The calibration documentation can be found as **Appendix I**.

Table 4 summarizes field measurement activities.

Table 3. FIELD MEASUREMENT ACTIVITIES		
Date and Time	Procedure ¹ , and Equipment	Measurer Name
December 19, 2023 9:25 a.m. – 10:35 p.m.	Region 7 procedure: <i>Photoionization Detector SOP</i> Equipment: Honeywell, PpbRae 3000, Serial No. 594-916195	Hunter Strom
¹ The current version of each procedure, at the time of the investigation, was followed.		

INVESTIGATION OBSERVATIONS AND POTENTIAL FINDINGS

I, or a team member under my direct supervision, made the following observations during the inspection.

These observations are not final compliance determinations. The EPA Region 7 Air Branch case review team will make the final compliance determinations based on its review of this report and other technical, regulatory, and facility information.

Mr. Fleischhacker informed me via email (**Appendix J**) on January 30, 2024, that the scrubbers at the facility were installed in the first half of 2021. According to the stack test report, the scrubbers were tested for removal efficiency on April 21-22 of 2022.

The operation and maintenance manual for the scrubbers states that the “Total EtO Treatment Capacity” is 290 pounds (lb). According to Mr. Swanger, the scrubber media is changed once every 6 months. Considering that there are four scrubbers, this would give a total EtO treatment capacity of 2,320 lb across the 12 aeration chambers each year. Based on the EtO annual usage logs, ACS used more than the total EtO treatment capacity each year. Some of the total EtO may be emitted as fugitive emissions. However, there is a possibility that the scrubber efficiency decreases due to an exceedance of the total EtO treatment capacity.

During the inspection, Mr. McElderry informed me that the pressure gauges for the scrubbers are checked twice per day. On December 19, 2023, Mr. McElderry informed me via email (**Appendix K**) that the scrubber pressure gauge readings have not been recorded.

Image IMG_0127.JPG shows that during the inspection, the pressure gauges for the scrubbers controlling aeration chambers 1-3 and 4-6 were blocked from being read due to product being

stored in front of the gauges. To get a photograph of the pressure gauge for the scrubber controlling aeration chambers 7-9, Mr. McElderry had to create a path through product stored in front of the gauge. The path created to get to the gauge can be seen in image IMG_0130.JPG.

Mr. McElderry provided me with the three most recent years of EtO usage records while I was on site. He informed me that the previous years were kept in an archive off site.

Outside of the facility, Mr. Strom and I observed a reading of 0.00 ppm measured as isobutylene on the PpbRae. In the storage area, Mr. Strom and I observed a reading of approximately 0.39 ppm measured as isobutylene on the PpbRae. Applying the response factor, this would indicate a reading of approximately 5.7 ppm if EtO were the only measured gas present. In the injection room, we observed a reading of approximately 0.08 ppm measured as isobutylene. Applying the response factor, this would indicate a reading of approximately 1.0 ppm if EtO were the only measured gas present. In the aeration chamber area, Mr. Strom and I observed a reading of approximately 0.35 ppm measured as isobutylene on the PpbRae. Applying the response factor, this would indicate a reading of approximately 4.6 ppm if EtO were the only measured gas present. 29 C.F.R. 1910.1047(c)(1) lists the Occupational Safety and Health Administration (OSHA) 8-hour time weighted average (TWA) as 1 ppm.

On December 21, 2023, I requested an initial notification to demonstrate compliance with § 63.366(c) from Mr. Swanger. Before receiving the document, Mr. Swanger informed me that he accepted a position with another company and suggested that I contact Ms. Nancy DuVal, Assistant General Counsel for Owens & Minor. I contacted Ms. DuVal, and she directed my request to Mr. Philip Fleischhacker, the Sr. Engineer and Technical Manager. I have not yet received this document.

Potential Finding 1: Failure to meet emission standards
Observation Summary: The facility is required to control emissions from sterilization chamber vents immediately upon initial startup of the source and failed to do so.
Citation: § 63.360(g)(2)
Evidence: Email from Mr. Fleischhacker (Appendix J) and 2019 EPA Inspection Report (Appendix L)
Description of Observation: Section 63.360(g)(2) states that “The owner or operating shall comply with the provisions of this subpart as follows: All sterilization chamber vents subject to the emission standards in § 63.362 with an initial startup date on or after December 6, 1998, immediately upon initial startup of the source.” Section 63.362(c) Table 1 states that “Each owner or operator of a sterilization source using 1 ton shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.”

Potential Finding 1: Failure to meet emission standards

Based on a previous inspection report conducted by EPA, the facility began operations at this site in 2016, which is after the December 6, 1998, date in the § 63.360(g)(2). The facility is required to meet the emission standard for sterilization chamber vents immediately upon startup.

Based on Mr. Fleischhacker's statement that the scrubbers were not installed until the first half of 2021, there was a period of time in which the sterilization chamber vents vented to atmosphere uncontrolled and were required to meet the emission standards in § 63.362.

Potential Finding 2: Failure to comply with compliance and performance provisions

Observation Summary: The facility is required to conduct an initial performance test within 180 days after the compliance date and did not do so.

Citation: § 63.363(a)(2)

Evidence: The scrubber stack test report (Appendix C)

Description of Observation:

Section 63.363(a)(2) states that "The owner or operator of all sources subject to these emissions standards shall complete the performance test within 180 days after the compliance date for the specific source as determined in § 63.360(g)."

As discussed in Potential Finding 1, the compliance date for ACS was in 2016 when the facility began operating. Based on the stack test report documentation submitted, the scrubbers did not receive an initial test until April 22, 2022, which is more than 180 days after the compliance date.

Potential Finding 3: Failure to comply with permit conditions

Observation Summary: The facility is required to monitor daily and document weekly the magnehelic gauges for the scrubbers and did not do so.

Citation: § 63.363(e) and Construction Permit Number 1982 Modified #4 AIRC-2021-48134, Section 12 (Appendix A)

Evidence: Email from Mr. McElderry (Attachment K)

Description of Observation:

Section 63.363(e) requires that facilities complying with emission limits under § 63.362 with a control technology other than acid-water scrubbers or catalytic or thermal oxidizers provide to the Administrator or delegated authority information describing the design and operation of the air pollution control system, including recommendations for the operating parameters to be monitored to demonstrate continuous compliance.

Section 12 of the construction permit lists Additional Limits which require that "the owner or operator shall follow the compliance plan submitted to Polk County on January 14, 2021 to demonstrate compliance per § 63.363(e). The compliance plan includes... Each Magnehelic gauge will be monitored daily and documented weekly."

Potential Finding 3: Failure to comply with permit conditions
Mr. McElderry informed me during the inspection that the magnehelic pressure gauges on the scrubbers were checked twice daily. In an email on December 19, 2023, he informed me that the pressure readings were not currently recorded.

Potential Finding 4: Failure to comply with permit conditions
Observation Summary: The facility is required to maintain EtO use records on site for five years and only had three years on site.
Citation: Construction Permit Number 1982 Modified #4 AIRC-2021-48134, Section 12 (Appendix A)
Evidence: Statement from Mr. McElderry
Description of Observation: Section 12 of the construction permit lists Additional Limits which require that the facility, on a monthly basis, record the amount of EtO used and calculate a 12-month rolling total. And it requires that “these records shall be kept on site for a minimum period of five years.” During the inspection, Mr. McElderry provided me with the three most recent years of EtO use records kept on site. He informed me that the older records were kept in archives off site.

End of report.