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.
2610 NE Industrial Drive, Suite 220
Kansas City, MO 64117
FRS# 110071642383

Inspection Date:
December 18, 2023

Christopher Appier, Inspector, ECAD, Air Branch

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CONTENTS

INSPECTION OVERVIEW 3
INSPECTION OBJECTIVE 3
FACILITY CONTACT INFORMATION 3
FACILITY OVERVIEW 3
FACILITY OPERATIONS SUMMARY 5
FIELD ACTIVITIES SUMMARY 5
Measurement Activities 7
INSPECTION OBSERVATIONS AND POTENTIAL FINDINGS 7

TABLES

Table 1. PROJECT TEAM MEMBERS 3
Table 2. FACILITY CONTACT INFORMATION 3
Table 3. EMISSION STANDARDS FOR ETO COMMERCIAL STERILIZERS 4
Table 4. FIELD MEASUREMENTS ACTIVITIES 6

APPENDICES

A Image Log
B Ethylene Oxide Usage Logs
C Stack Test Report
D Scrubber Operating and Maintenance Manual
E Scrubber Media Change Log
F Confidential Business Information Form
G Receipt for Documents Form
H Guideline for PID Instrument Response
I PpbRae Calibration Documentation
J Email from William Swanger – Scrubber Installation Date

This Contents page shows all the sections contained in this report and provides a clear indication of the end of this report.

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). The inspection was part of the U.S. Environmental Protection Agency's (EPA) Reducing Air Toxics in Overburdened Communities National Enforcement Compliance Initiative. 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**
Roger Barnett, Operations Manager	(816) 207-8597	Roger.Barnett@owens-minor.com
William Swanger, Director, Environmental, Health, and Safety	(480) 645-2430	William.Swanger@hyh.com
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 in business since 2013 and has 48 employees. The facility operates from 5:00 a.m. through 1:30 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 MACT O listed below are relevant to the observations made during this inspection.

Section 63.367 requires that facilities record their 12-month rolling average EtO usage if they are not subject to the emission standards in § 63.362. Section 63.367 also requires that records be "maintained in such a manner that can be readily accessed and are suitable for inspection. The most recent 2 years of records shall be retained onsite or shall be accessible to an inspector while onsite. The records of the preceding 3 years, where required, may be retained offsite."

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)(1) states that "The owner or operator of a source subject to emissions standards in § 63.362 shall conduct an initial performance test using the procedures listed in § 63.7 according to the applicability in Table 1 of § 63.360, the procedures listed in this section, and the test methods listed in § 63.365."

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.

ACS is an area source and does not have an air permit because § 63.360(f) provides an exemption from the obligation to obtain a permit for this reason alone.

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 (IMG_0110.JPG, **Appendix A**). The medical equipment is placed inside semi-permeable sterilization bags in the Breakdown and Assembly Room. An example of an assembled bag can be seen in images IMG_0113.JPG – IMG_0115.JPG. These bags are then taken to the Injection Room where they are filled with EtO using an in-house designed A-BIO-VAC unit, which can be seen in images IMG_0111.JPG & IMG_0122.JPG. 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_0116.JPG shows the outside of an aeration chamber and image IMG_0121.JPG shows the inside of a chamber filled with product. The aeration chambers, of which there are 12, are humidity and temperature controlled automatically 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. One of the scrubbers can be seen in image IMG_0117.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 18, 2023, at 9:05 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. Roger Barnett, the operations manager, at 9:25 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. 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. I explained to Mr. Barnett that the facility would have an opportunity to make a claim of business confidentiality at the end of the inspection.

I was given a facility tour by Mr. Barnett, during which he explained the details of the facility operations. During the facility tour, Mr. Strom conducted ambient air measurements 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. 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. Last, we observed the aeration chambers and the scrubbers used to control their emissions.

After the facility tour, I met with Mr. Barnett in a conference room and requested several documents to demonstrate compliance with MACT O. Mr. Barnett called Mr. William Swanger, the Director of Environmental, Health, and Safety, via speakerphone to help locate documents. Mr. Barnett was able to provide me with EtO usage records from January 2023 through mid-December 2023 (**Appendix B**). Mr. Swanger provided me with a map of the property, a stack test report for the scrubbers from April 19, 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. Barnett. 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. Mr. Barnett did not make a claim of confidentiality.

Observations and potential findings from the facility tour, 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.

Table4. FIELD MEASUREMENT ACTIVITIES		
Date and Time	**Procedure[1], and Equipment**	**Measurer Name**
December 18, 2023 9:25 a.m. – 10:35 a.m.	**Region 7 procedure:** *Photoionization Detector SOP* **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.

When asked to provide EtO usage records for 2018-2023, Mr. Barnett and Mr. Swanger were only able to provide records from January 2023 up to the date of the inspection. Mr. Barnett informed me that ACS employees were not previously keeping track of this information and that he recently began compiling information to determine prior EtO usage records. He informed me that he would begin working on records for 2018-2022 and provide them to me when completed. To the date of this inspection report, these records have not been provided.

Mr. Barnett informed me that he believed the facility began operations around the year 2013 but was not sure on the exact date.

Mr. Swanger informed me that employees at the facility do not have a standard operating procedure (SOP) for checking the differential pressure gauges on the scrubbers and do not record any readings. He stated that they are working on creating an SOP.

Mr. Swanger informed me that there were no malfunctions of the scrubbers to report. He also informed me that no alternative control technology information had been submitted.

Mr. Swanger informed me via email (**Appendix J**) on December 19, 2023, that the scrubbers at the facility were installed in May of 2021, but due to issues with the city and power company, did not start-up until June of 2022. However, as noted below, three of the scrubbers were tested for removal efficiency on April 19, 2022.

During the April 19, 2022, stack testing event, only scrubbers 2-4 were tested. The stack test report states that "scrubber 1 and aeration chambers 1-3 were not in operation at the time of the test due to a maintenance issue." The report does not clarify if it was the scrubbers and/or the aeration chambers that were the source of the issues. I did not receive any documentation demonstrating control efficiency for scrubber 1. In addition, the report does not contain any operating parameter values that could be used to establish operating parameter operating limits.

The operation and maintenance manual for the scrubbers states that the "Total EtO Treatment Capacity" is 290 pounds (lb). According to Mr. Barnett and 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 2023 EtO annual usage log, ACS had used 3,618 lb of EtO from January 1 – Dec 13. 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.

For example, the scrubber media change log shows that the media was replaced in February of 2023 and next in August of 2023. For this time period, the total EtO treatment capacity would be 1,160 lb across all four scrubbers. Conservatively assuming that the scrubber media changes were conducted on February 28 and August 1, ACS used 1,674 lb EtO between March and July of 2023. Additionally, the scrubber media change log shows that in May of 2022 there was a media replacement, and that the next replacement was not completed until February of 2023.

In the shipping area, Mr. Strom and I observed a reading of approximately 0.30 ppm measured as isobutylene on the PpbRae. Applying the response factor, this would indicate a reading of

approximately 3.9 ppm if EtO were the only measured gas present. In the injection room, we observed a reading of approximately 0.25 ppm measured as isobutylene. Applying the response factor, this would indicate a reading of approximately 3.3 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 from Mr. Swanger an initial notification to demonstrate compliance with § 63.366(c). 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: Statements from Mr. Barnett and Mr. Swanger
Description of Observation: Section 63.360(g)(2) states that "The owner or operator 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." Based on Mr. Barnett's statement that the facility began operating in 2013, 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. Swanger's statement that the scrubbers were not fully operational until June of 2022, 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 to demonstrate compliance with emission standards and to establish operating limits for control devices and did not do so for scrubber 1.
Citation: § 63.363(a)(1)
Evidence: The scrubber stack test report (Appendix C)

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

Description of Observation:

Section 63.363(a)(1) states that "The owner or operator of a source subject to emissions standards in § 63.362 shall conduct an initial performance test using the procedures listed in § 63.7 according to the applicability in Table 1 of § 63.360, the procedures listed in this section, and the test methods listed in § 63.365."

In the "Introduction" section of the stack test report, it is stated that "The control devices tested included three of the four AAT Safe Cell II dry scrubbers, which are currently used to control emissions from nine aeration chambers (P4-P12). Dry scrubber #1 and aeration chambers 1-3 were not in operation at the time of the test due to a maintenance issue."

Based on the documentation submitted, it appears that scrubber 1 has not had an initial performance test conducted to demonstrate compliance with the emission standards and to establish operating limits.

Potential Finding 3: 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 2013 when the facility began operating. Based on the stack test report documentation submitted, scrubbers 2-4 did not receive an initial test until April 19, 2022.

Potential Finding 4: Failure to comply with compliance and performance provisions

Observation Summary: The facility is required to provide information on the air pollution control system to allow the Administrator to determine operating parameters and operating limits for the operating parameters.

Citation: § 63.363(e)

Evidence: Statement from Mr. Swanger, the scrubber stack test report (Appendix C), and the operating and maintenance manual for the scrubbers (Appendix D)

Description of Observation:

Section 63.363(e) states that "For facilities complying with the emissions limits under § 63.362 with a control technology other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator of the facility shall provide to the Administrator or delegated authority information describing the design and operation of the air pollution

Potential Finding 4: Failure to comply with compliance and performance provisions

control system, including recommendations for the operating parameters to be monitored to demonstrate continuous compliance. Based on this information, the Administrator will determine the operating parameter(s) to be measured during the performance test. During the performance test required in paragraph (a) of this section, using the methods approved in § 63.365(g), the owner or operator shall determine the site-specific operating limit(s)for the operating parameters approved by the Administrator."

According to the operating and maintenance manual documentation submitted, the air pollution control systems are Safe-Cell II Model DR-490 dry bed scrubbers. The air pollution control systems are not acid-water scrubbers or catalytic or thermal oxidizers.

During the inspection, Mr. Swanger informed me that the facility had not submitted any information regarding alternative control technology. I also observed that the stack test report did not contain any operating parameters that would be used to monitor the performance of the scrubbers, such as differential pressure.

Based on the information above, it appears that neither the operating parameters or operating limits for the operating parameters have been established or approved.

End of report.