

Georgia Department of Natural Resources

Environmental Protection Division • Air Protection Branch

4244 International Parkway • Suite 120 • Atlanta • Georgia 30354

404/363-7000 • Fax: 404/363-7100

Judson H. Turner, Director

Compliance Monitoring Report

1. General Information

Date of Inspection: May 21, 2015
Date of Report Completed: May 27, 2015
Compliance Monitoring Category: Unannounced Inspection
Inspector Name: Don Holder
Reviewing Manager: Michael Odom

2. Facility Information

Facility Name: Bard Medical Division, Covington
Facility AIRS No.: 217-00021
Facility Location: 8195 Industrial Blvd.
Covington, Georgia 30014 (Newton County)
Facility Mailing Address: Same as above
Facility Contact: John LaMontagne
Manager, Facility Engineering
770-784-6186
john.lamontagne@crbard.com
CMS Designation: Synthetic Minor Source

Air Quality Permit No. 3841-217-0021-S-03-0

Effective Date: April 8, 2010

Issued for the operation of an ethylene oxide sterilization facility. Construction and operation of a new sterilization line to include one new sterilization vessel and two new aeration cells.

Permit(s) can be accessed at www.georgiaair.org

3. Inspection Summary / Recommended Actions:

The facility appeared to be in compliance with the conditions of the permit at the time of the inspection.

4. Previous Enforcement Actions and Inspections:

There have been no enforcement actions for this facility during the previous five years.

5. Complaint Investigations since last Full Compliance Evaluation:

No complaints have been received for this facility during the previous five years.

6. Applicable Requirements, Description of Regulated Emission Units, and Inspection Determinations:

Emission Units		Corresponding Permit Conditions	Air Pollution Control Devices		Inspection	
ID No.	Description		ID No.	Description	Evaluated During Inspection?	Inspection Determination
SV1	Sterilization Vessel # 1	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 2.6, 3.1, 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.4, 6.8, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 8.2	RTO-1	Regenerative Thermal Oxidizer	Yes	No compliance issues noted.
SV2	Sterilization Vessel # 2	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 2.6, 3.1, 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.4, 6.8, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 8.2	RTO-1	Regenerative Thermal Oxidizer	Yes	No compliance issues noted.
SV3	Sterilization Vessel # 3	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 2.6, 3.1, 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.4, 6.8, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 8.2	RTO-1	Regenerative Thermal Oxidizer	Yes	No compliance issues noted.
SV4	Sterilization Vessel # 4	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 2.6, 3.1, 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.4, 6.8, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 8.2	RTO-1	Regenerative Thermal Oxidizer	Yes	No compliance issues noted.
SV5	Sterilization Vessel # 5	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 2.6, 3.1, 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.4, 6.8, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 8.2	RTO-1	Regenerative Thermal Oxidizer	Yes	No compliance issues noted.

Emission Units		Corresponding Permit Conditions	Air Pollution Control Devices		Inspection	
ID No.	Description		ID No.	Description	Evaluated During Inspection?	Inspection Determination
A1A	Aeration Cell 1A	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.4, 2.5, 2.6, 3.1, 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.4, 6.8, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 8.2	RTO-1	Regenerative Thermal Oxidizer	Yes	No compliance issues noted.
A2A	Aeration Cell 2A	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.4, 2.5, 2.6, 3.1, 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.4, 6.8, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 8.2	RTO-1	Regenerative Thermal Oxidizer	Yes	No compliance issues noted.
A3A	Aeration Cell 3A	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.4, 2.5, 2.6, 3.1, 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.4, 6.8, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 8.2	RTO-1	Regenerative Thermal Oxidizer	Yes	No compliance issues noted.
A4A	Aeration Cell 4A	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.4, 2.5, 2.6, 3.1, 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.4, 6.8, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 8.2	RTO-1	Regenerative Thermal Oxidizer	Yes	No compliance issues noted.
A5A	Aeration Cell 5A	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.4, 2.5, 2.6, 3.1, 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.3, 6.4, 6.8, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 8.2	RTO-1	Regenerative Thermal Oxidizer	Yes	No compliance issues noted.
A1B	Aeration Cell 1B	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.4, 2.5, 2.6, 3.1, 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.4, 6.8, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 8.2	RTO-1	Regenerative Thermal Oxidizer	Yes	No compliance issues noted.
A2B	Aeration Cell 2B	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.4, 2.5, 2.6, 3.1, 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.4, 6.8, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 8.2	RTO-1	Regenerative Thermal Oxidizer	Yes	No compliance issues noted.
A3B	Aeration Cell 3B	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.4, 2.5, 2.6, 3.1, 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.4, 6.8, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 8.2	RTO-1	Regenerative Thermal Oxidizer	Yes	No compliance issues noted.
A4B	Aeration Cell 4B	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.4, 2.5, 2.6, 3.1, 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.4, 6.8, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 8.2	RTO-1	Regenerative Thermal Oxidizer	Yes	No compliance issues noted.

Emission Units		Corresponding Permit Conditions	Air Pollution Control Devices		Inspection	
ID No.	Description		ID No.	Description	Evaluated During Inspection?	Inspection Determination
A5B	Aeration Cell 5B	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.4, 2.5, 2.6, 3.1, 4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.3, 6.4, 6.8, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 8.2	RTO-1	Regenerative Thermal Oxidizer	Yes	No compliance issues noted.

7. Compliance Monitoring Activities – Details not included in table above:

a. Describe any deviation from compliance noted during the inspection listed on Table 6:

No deviations noted during inspection.

b. Describe any compliance assistance provided during inspection:

No compliance assistance was required.

c. Describe any action taken by the facility to come back into compliance during the inspection:

None.

d. Deviations noted during the inspection, not previously listed. Include equipment ID or equipment description and condition number:

No deviations observed.

8. Additional Permit Requirements:

- a. Periodic Reports:
Facility has submitted all required reports.
See attached Full Compliance Evaluation (FCE) Report for details.

- b. Permit Fees:
Facility has paid all required fees.
See attached Full Compliance Evaluation (FCE) Report for details.

- c. Permit Renewal and Expiration:
Not Applicable.

- d. For any overall emission/production/usage limit:

Table 8.d.		
Permit Condition	Permit Limit	Actual
2.1	Comply with requirements of 40 CFR Part 63, Subpart O.	Facility is in compliance with Subpart O.
2.3	Reduce ethylene oxide emissions from each sterilizer chamber by at least 99%.	Testing conducted on July 16, 2012.
2.4	Reduce ethylene oxide emissions from each aeration chamber to 1 ppm or by at least 99%.	Testing conducted on July 16, 2012.

9. Attachments:

- a. Inspection Observations:
See attachment

- b. Performance Tests:
No routine testing is required for this source.
See attachment

- c. Full Compliance Evaluation (FCE) Report:
See attachment

Attachment: Inspection Observations

Fugitive Emissions

Permit Condition	Permit Limit	Observation
3.1	Take all reasonable precautions with any operation, process, handling, transportation or storage facility to prevent fugitive emissions.	No fugitive emissions observed during inspection.

Process & Control Equipment

Permit Condition	Permit Limit	Observation
4.1	Operate Regenerative Thermal Oxidizer (RTO-1) at or above 1447°F. An operating parameter deviation is defined as any 24-hour average of the oxidation temperature for the Regenerative Thermal Oxidizer (RTO-1) that is below 1447 °F.	Facility operates at set point of 1472° F as determined from testing.
4.2	Conduct routine maintenance on all air pollution control equipment.	Routine maintenance conducted on control equipment.
4.3	Maintain spare parts inventory for all control equipment.	Routine spare parts for all control equipment on site.
4.4	Malfunctioning components of air pollution control systems shall be repaired as expeditiously as possible.	All repairs made as soon as possible.

Monitoring

Permit Condition	Monitoring Requirement	Observation
5.1	Continuously monitor and record the oxidation temperature using the temperature monitor(s) described in Condition 5.2 or measure and record the ethylene oxide concentration in accordance with §63.364(e).	Temperatures recorded continuously. Strip charts used as backup recorders.
5.2	Install, calibrate, maintain, and operate a system to continuously monitor and record the oxidation	Temperature monitoring system installed and operational.

	temperature as determined from the average reading of the three combustion chamber temperature sensors on the Regenerative Thermal Oxidizer (RTO-1). The temperature monitor shall be accurate within ± 5.6 degrees Celsius (± 10 degrees Fahrenheit).	
5.3	Verify the accuracy of the temperature monitor twice each calendar year	Temperature probe replaced semi-annually.
5.4	All monitoring systems shall be in continuous operation. Maintenance and repair shall be conducted to minimize periods of non-service.	All systems operating continuously.
5.5	Maintain spare parts inventory for all monitoring equipment.	Spare parts available for monitors.

Performance Testing

Permit Condition	Testing Requirement	Observation
6.1	Conduct performance test as directed by the Division.	Not required.
6.2	Within 60 days but not later than 180 days after startup, conduct ethylene oxide testing for Sterilization Vessel # 5 (Source Code SV5) to determine compliance with the emission limit in Condition 2.3.	Completed on July 16, 2012. 99.97% destruction efficiency.
6.3	Within 60 days but not later than 180 days after startup, conduct ethylene oxide testing for Aeration Cell 5A (Source Code A5A) and Aeration Cell 5B (Source Code A5B) to determine compliance with the emission limit in Condition 2.4.	Completed on July 16, 2012. 99.50% destruction efficiency.

Notification, Reporting and Record Keeping

Permit Condition	Permit Limit	Observation
7.1	Maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, any malfunction of the air pollution control equipment or any periods during which a continuous monitoring system or monitoring device is inoperative for 5 years.	All records on file as required.
7.2	Notify EPD of any malfunction or breakdown of equipment for over four hours that results in excessive emissions. Notify within 7 days.	None to report.
7.3	Maintain a file of all measurements required by this permit, including continuous monitoring system, monitoring device, and performance testing measurements; all continuous monitoring system performance evaluations; all continuous monitoring system or monitoring device calibration checks; adjustments and maintenance performed on these systems or devices; and all other information required by this part recorded in a permanent form suitable for inspection for five years.	Temperature logs on file. Calibration logs for temperature probes on file.
7.4	The data acquisition system for the temperature monitors required by Condition 5.2. shall compute and record a daily average oxidation temperature from the 15-minute or shorter period temperature values. Strip chart data shall be converted to record a daily average oxidation temperature for each day any instantaneous temperature recording falls below the minimum temperature.	All data collected as required.
7.5, 7.6	Maintain files of all information required by this permit or by 40 CFR 63 in a form suitable and available for expeditious inspection and review for at least five years. Maintain General records and CMS records as specified by 40 CFR 63.10(b)(2) and (c), respectively, and Table 1 of 40 CFR 63 Subpart O.	All data on file as required.
7.7	Submit the following reports: a. Deviation reports; and b. Continuous Monitoring System performance and summary reports	All reports submitted. No issues reported.
7.8	Submit semi-annual report of reportable incidences to EPD containing the nature and cause of the deviation, the time and date of occurrence, and any initial and final corrective action taken. The report	Semi-annual reports submitted as required. No deviations reported.

	<p>shall also contain a summary of any days for which any of the required operation and maintenance surveillance checks were not made and the reason for such failure to perform the surveillance containing:</p> <ol style="list-style-type: none"> a. A summary report of excess emissions, exceedances and excursions, and monitor downtime, in accordance with Section 1.5(c) and (d) of the above referenced document, including any failure to follow required work practice procedures. b. Total process operating time during each reporting period. c. The magnitude of all excess emissions, exceedances and excursions computed in accordance with the applicable definitions as determined by the Director, and any conversion factors used, and the date and time of the commencement and completion of each time period of occurrence. d. Specific identification of each period of such excess emissions, exceedances, and excursions that occur during startups, shutdowns, or malfunctions of the affected facility. Include the nature and cause of any malfunction (if known), the corrective action taken or preventive measures adopted. e. The date and time identifying each period during which any required monitoring system or device was inoperative (including periods of malfunction) except for zero and span checks, and the nature of the repairs, adjustments, or replacement. When the monitoring system or device has not been inoperative, repaired, or adjusted, such information shall be stated in the report. f. Certification by a Responsible Official that, based on information and belief formed after reasonable inquiry, the statements and information in the report are true, accurate, and complete. 	
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7.9	<p>Furnish the following notifications:</p> <ul style="list-style-type: none"> a. The date of construction of Sterilization Vessel # 5 (Source Code: SV5), Aeration Cell 5A (Source Code: A5A), and Aeration Cell 5B (Source Code: A5B) no later than 30 days after such date. b. The anticipated date of initial startup of Sterilization Vessel # 5 (Source Code: SV5), Aeration Cell 5A (Source Code: A5A), and Aeration Cell 5B (Source Code: A5B), not more than 60 nor less than 30 days prior to such date. c. The actual date of initial startup of Sterilization Vessel # 5 (Source Code: SV5), Aeration Cell 5A (Source Code: A5A), and Aeration Cell 5B (Source Code: A5B) within 15 days after such date. d. Certification that a final inspection has shown that construction has been completed in accordance with the application, plans, specifications, and supporting documents submitted in support of this Permit. 	All notifications submitted as required.
8.2	Pay permit fees.	All fees paid.

Attachment: Performance Tests

Source Tested	Pollutant	Date of Test	Required Testing Frequency	Limit	Actual
Sterilization Vessel #5	Ethylene Oxide	7/18/12	Upon start-up	99% control of inlet gas	99.97%
Aeration Chamber Cells 5A and 5B	Ethylene Oxide	7/18/12	Upon start-up	1 ppm or 99% control of inlet gas	0.7 ppm 99.50%