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:	April 14, 2016
Date of Report Completed:	April 19, 2016
Compliance Monitoring Category:	Planned Unannounced
Inspector Name:	Don Holder
Reviewing Manager:	Mike Odom

2. Facility Information

Facility Name:	C. R. Bard, Incorporated Madison
Facility AIRS No.:	211-00021
Facility Location:	1211 Mary Magnan Boulevard Madison Georgia 30650 (Morgan County)
Facility Mailing Address:	8195 Industrial Boulevard Covington, Georgia 30014
Facility Contact:	John Lamontagne Facility Engineering Manager (770)784-6186 john.lamontagne@crbard.com
CMS Designation:	Synthetic Minor Source

Air Quality Permit No. **3841-211-0021-S-03-0** **Effective Date: March 6, 2009**

Issued for the operation of a commercial sterilization facility and a regenerative thermal oxidizer. Construction and operation of a new sterilization process to include one new sterilization chamber 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 requirements of the Permit at the time of the inspection.

4. Previous Enforcement Actions:

There have been no previous enforcement actions.
See attached Full Compliance Evaluation (FCE) Report for details.

5. Complaint Investigations since last Full Compliance Evaluation:

No complaints have been received for this facility.
See Complaint Tracking System (CTS) for further details.

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 Sv2 SV3 SV4 SV5 SV6 SV7	Sterilizer Chamber Vents	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, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 6.1, 6.2, 6.4, 6.5, 6.6, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 7.10, 7.11, 7.12	RTO1 – Regenerative Thermal Oxidizer		Yes	No issues noted.
A1A/B A2A/B A3A/B A4A/B A5A/B A6A A7A/B	Aeration Chamber Vents	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, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 6.1, 6.3, 6.4, 6.5, 6.6, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 7.10, 7.11, 7.12	RTO1 – Regenerative Thermal Oxidizer		Yes	No 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 5:

No deviations noted during the inspection.

b. Describe any compliance assistance provided during inspection:

No compliance assistance needed.

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:

None.

8. Additional Permit Requirements:

a. Periodic Reports:
All semi-annual reports submitted as required.
See attached Full Compliance Evaluation (FCE) Report for details.

b. Permit Fees:
All permit fees paid as required.
See attached Full Compliance Evaluation (FCE) Report for details.

c. Permit Renewal and Expiration
Not Applicable.

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

Permit Condition	Permit Limit	Actual
2.3	Reduce EO emissions from sterilizer chamber vents by 99%.	Initial testing conducted on June 14-15, 2007. Emissions reduced by 99.9993%.
2.4	Reduce EO emissions from sterilizer chamber vents to 1ppm by volume or less or by at least 99%.	Initial testing conducted on June 14-15, 2007. Emissions reduced by 99.4%.

9. Attachments:

a. Inspection Observations:
See attachment

b. Performance Tests:
See attachment

c. Enforcement History
See attachment

d. Full Compliance Evaluation (FCE) Report:
See attachment

Attachment A: Inspection Observations

Fugitive Emissions

Permit Conditions		Inspection
3.1	The Permittee shall take all reasonable precautions with any operation, process, handling, transportation, or storage facilities to prevent fugitive emissions of air contaminant.	No fugitive emissions were observed.

Process and Control Equipment

Permit Conditions		Inspection
4.1	Routine maintenance shall be performed on all air pollution control equipment. Said maintenance records shall be maintained in a form suitable and available for inspection by the Division for no less than five years from the date of last entry.	Maintenance conducted in-house and by vendor. Maintenance activities conducted on monthly, quarterly and annual schedule.
4.2	Operate RTO1 at or above temperature established during most recent testing.	Temperatures during most recent testing were 1454°F for chamber vents and 1398 for aeration vents. EPD approved an oxidizer operating temperature of 1400°F at the introduction of vent gases on January 20, 2009. This was based on historic data that showed increases in operating temperatures as a result of the introduction of ethylene oxide gases to the oxidizer. Oxidizer temperature after EO injection ranges from 1440°F to 1460°F.

Monitoring Requirements

Permit Conditions		Inspection
5.1	Measure and record the ethylene oxide concentration in accordance with §63.364(e) or continuously monitor and record the oxidation temperature using the temperature monitor(s) described in Condition 5.2. Monitoring is required only when the Regenerative Thermal Oxidizer (RTO1) is operated.	Oxidizer has digital data logger. Readings from three probes every 15 minutes and are averaged to determine the three-hour oxidation temperatures. Temperature probes replaced with new probes quarterly. Facility uses a strip chart backup system. If monitor goes out, entire system will be shut down.
5.2	Install, calibrate, maintain, and operate a system to continuously monitor and record the oxidation 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).	Monitoring system is in place and operating properly. Quarterly accuracy checks conducted. Thermocouples replaced quarterly.
5.3	Verify the accuracy of the temperature monitor required by Condition No. 5.2 twice each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose).	The temperature monitor was last calibrated on March 11, 2016. Calibrations are conducted quarterly.
5.4	Develop and implement a CMS quality control program (which includes a CMS performance evaluation) as specified in 40 CFR 63.8(d) and (e).	Quality control program is in place.
5.5	All monitoring system installed shall be in continuous operation except during calibration checks, zero and span adjustments or periods of repair. Maintenance or repair shall be conducted in the most expedient manner to minimize the period during which the system is out of service.	Monitoring systems installed and operational.
5.6	Maintain a spare parts inventory for any monitoring equipment.	The only spare parts are new temperature probes.

Performance Tests:

Permit Conditions		Inspection
6.2	Within 180 days after initial startup of Sterilization Chamber 7 (Source Code SV7), conduct ethylene oxide performance testing to determine compliance with the emission limit in Condition 2.2.	Chamber 7 is to be installed during April/May 2016.
6.3	Within 180 days after initial startup of Aeration Room 7 (Source Code A7A/B), the Permittee shall conduct ethylene oxide performance testing to determine compliance with the emission limit in Condition 2.3	Chamber 7 is to be installed during April/May 2016.

Notification, Reporting and Recordkeeping:

Permit Conditions		Inspection
7.1	The Permittee shall maintain records for five years 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.	All records are on file as required.
7.2	In the event of any malfunction or breakdown of process or emission control equipment for a period of four hours or more which results in excessive emissions, the owner or operator shall submit a written report which describes the cause of the breakdown, the corrective actions taken, and the plans to prevent future occurrences. This report must be submitted by means that would ensure the Division's receipt of the report by no later than seven days after the occurrence	There were no incidences to report.
7.3	Maintain a file of all measurements, 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 Permit. The information shall be recorded in a permanent form suitable and available for inspection and shall be retained for at least five (5) years following the date of such measurements maintenance, reports, and records.	All data is on file as required.
7.4	Submit a site-specific test plan along with the Notification of Intent to conduct a performance test.	Not required at this time.
7.5	Submit the results of a performance test and notification of compliance status within 60 days following completion of the test.	Not required at this time.

7.6	Submit the following reports: a. Deviation reports; and b. Continuous Monitoring System performance and summary reports Contents and submittal dates for Deviation and Continuous Monitoring System Performance Reports shall be as specified in 40 CFR 63.366(a)(3).	All reports submitted as required. 7/30/2015 1/26/2016
7.7	Maintain files of all information required in a form suitable and available for inspection and review for at least five years.	All data is on file as required.
7.8	Maintain General records and Continuous Monitoring System records as required.	All records are on file as required.
7.9	Furnish the Division written notification as follows: a. The date of construction of the Sterilization Vessel 7 (Source Code: SV7) and the Aeration Chamber 7 (Source Code: A7a/b) no later than 30 days after such date. b. The anticipated date of initial startup of the Sterilization Vessel 7 and the Aeration Chamber 7 , not more than 60 nor less than 30 days prior to such date. c. The actual date of initial startup of the Sterilization Vessel 7 and the Aeration Chamber 7 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.	Chamber 7 is to be installed during April/May 2016.
7.10	Compute and record a daily average oxidation temperature from 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.	Data has been collected and daily average temperatures are recorded.
7.11	Submit a written report containing any excess emissions, exceedances, and/or excursions and any monitor malfunctions for each semiannual period ending June 30th and December 31st of each year. All reports shall be postmarked by the 30th day following the end of each reporting period, July 30th and January 30th. In the event that there have not been any excess emissions, exceedances, excursions, or malfunctions during a reporting period, the report should so state. Otherwise, the contents of each report shall be as specified by the Division's Procedures for Testing and Monitoring Sources of Air Pollutants and shall contain the following: [391-3-1-.02(6)(b)1, 40 CFR 63.10(e)] 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	All reports have been submitted as required.

	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.	
7.12	Operating parameter deviations are defined as follows: a. Any 24-hour average of the oxidation temperature for the Regenerative Thermal Oxidizer (RTO1) that is below the temperature specified in Condition 4.2.	No deviations reported.