

Air Protection Branch

4244 International Parkway
Suite 120
Atlanta, Georgia 30354
404-363-7000

Compliance Monitoring Report

1. General Information

Date of Inspection: November 8, 2019
Date of Report Completed: November 12, 2019
Compliance Monitoring Category: Unannounced Investigation
Inspector Name: Stephen Damaske/Tammy Martiny
Reviewing Manager: Sean Taylor

2. Facility Information

Facility Name: BD (Becton, Dickinson and Company)
Facility AIRS No.: 211-00021
Facility Location: 1211 Mary Magnan Boulevard
Madison, Georgia 30360, Morgan County
Facility Mailing Address: 8195 Industrial Boulevard
Covington, Georgia 30014
Facility Contact: John LaMontagne
Process Technology Engineer
(770) 784-6186
john.lamontagne@crbard.com
CMS Designation: Synthetic Minor Source

Air Quality Permit No. 3841-211-0021-S-04-0

Effective Date: January 9, 2019

Issued for the operation of a commercial sterilization facility and a regenerative thermal oxidizer, and for the purpose of establishing practically enforceable emission limitations such that the facility will not be considered a major source with respect to Title V of the Clean Air Act Amendments of 1990.

Permit(s) can be accessed at <https://permitsearch.gaepd.org/>

3. Inspection Summary / Recommended Actions:

This inspection was performed to verify compliance with Civil Action File No. SUCV2019002219 from the Superior Court of Newton County State of Georgia filed in open court October 28, 2019. Specifically, the inspection was pertaining to conditions in Attachment A that pertained to the BD Madison Facility (Conditions 2, 7, 14, 15, 16, and 18). The Company had appropriate records for each of the conditions pertaining to the facility from the order. Records are attached showing progress toward meeting condition timelines. The facility appeared in compliance with all conditions of the Consent Order at the time of inspection.

4. Previous Enforcement Actions and Inspections:

No previous enforcement. Last air permit inspection was completed April 14, 2016.

5. Complaint Investigations since last Full Compliance Evaluation:

No complaints received.

6. Attachments:

- a. Inspection Observations
- b. Training Records for weekday operators to show personnel have been trained in 24-hour aeration times for all cycles.
- c. Leak Detection and Repair (LDAR) forms. One draft partially completed for the week of 11/6/19 and one blank for reference.
- d. Record of Monthly Lots July – September 2019
- e. Record of Lots Sterilized since November 1

Attachment: Inspection Observations

Stephen Damaske and Tammy Martiny arrived at the site at 7:50 am. The facility operates 24 hours a day, but office hours are from 8:00 am to 5:00 pm. We waited in our vehicle and began the inspection at 8:05 am. We were greeted by Jennifer Adamson, Operations Supervisor. She informed us that Frank Garriott, Operations Manager, and John LaMontagne, Process Technology Engineer, were on their way in and would be able to assist us. When Mr. LaMontagne arrived, he checked our credentials and we began discussing our reason for visiting the facility. We stated we were there to complete an inspection based on the Consent Order specifically the conditions in Attachment A that applied to the Madison facility.

Condition 2 requires all unpermitted releases to be reported to EPD. Mr. LaMontagne stated there were none that he was aware of. Mr. Boone Brothers joined us later and stated there had been no releases from the facility.

Condition 7 required training of staff that aeration cycle times were changed to 24 hours and confirmation by a third party that changes had been made to process and throughput change. The facility provided documentation that staff had been trained on 24-hour aeration cycles for personnel who work during the week. They stated that weekend staff would be trained as they came on starting that evening. Ramboll was the 3rd Party company that was coming out November 9th to verify the changes in the computer software to make all cycles aeration time 24 hours. The Programming for the cycles had been updated October 29, 2019 and the training of personnel for manual overrides was started November 5 and in process. See attached sign in sheets for further details.

Condition 14 required a leak detection and repair program at both facilities to check all outside components for leaks with weekly monitoring. The program had begun on November 6 at Madison and they had currently completed 5 out of 7 lines with leak detection. Records are attached of the unverified partial inspection and a blank copy for reference. We discussed setting a reporting limit and what determines a leak that would need to be reported. We determined that more discussion was required, but on-going communication about what was found during inspections would be appropriate.

Condition 15 requires BD Madison to not increase EtO usage greater than usage during Months of July, August and September until after BD Covington has their permit issued. Records were received to show Lots of product sterilized in July, August and September to be 568, 614, and 626 respectively. This averages to 603 lots per month. The current lots since November 1 are 138.5 for 8 days of 30 days in November. This averages to 519 lots in November at current rate and show compliance with this condition.

Condition 16 requires submittal of weekly reports of daily lots sterilized, ethylene oxide usage, EtO destroyed in RTO, and sterilization cycle reports to demonstrate 24 hours of aeration time for both facilities. The reports have been submitted timely and completely for compliance with this condition.

Condition 18 requires BD to submit a complete application for BD Madison on or before December 15, 2019. The facility indicated they are on track to meet this deadline with the initial design meeting scheduled for November 14, 2019.

The Facility appeared to be in compliance with all conditions during the inspection and will continue to communicate with the Division about each condition as timelines become due.

Emission Unit	Control Device	Parameter Monitor	Permit Limit	Current Inspection
PB01	RTO	24-Hr Average Combustion Temperature	Last performance test temperature 1449 °F ±10 °F	1443 °F 24-hour average