



GEORGIA

DEPARTMENT OF NATURAL RESOURCES

ENVIRONMENTAL PROTECTION DIVISION

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NARRATIVE

TO: Heather Brown
 FROM: Joe Aisien
 DATE: December 13, 2018

Facility Name: **BD (Becton, Dickinson and Company)**
 AIRS No.: 21100021
 Location: Madison, GA (Morgan County)
 Application #: 26804
 Date of Application: October 29, 2018

Background Information

This facility sterilizes packaged medical equipment from other locations using ethylene oxide. After sterilization, the ethylene oxide is displaced with air and vented to a regenerative thermal oxidizer (RTO) for destruction.

Purpose of Application

The purpose for this application is for ownership change from C.R. Bard, Incorporated Madison to BD (Becton, Dickinson and Company). BD acquired C.R. Bard, Incorporated on December 29, 2017.

Updated Equipment List

Emission Units			Associated Control Devices	
Source Code	Description	Installation Date	Source Code	Description
SV1	Sterilization Chamber # 1	2006	RT01	Regenerative Thermal Oxidizer
SV2	Sterilization Chamber # 2	2006	RT01	Regenerative Thermal Oxidizer
SV3	Sterilization Chamber # 3	2006	RT01	Regenerative Thermal Oxidizer
SV4	Sterilization Chamber # 4	2006	RT01	Regenerative Thermal Oxidizer
SV5	Sterilization Chamber # 5	2006	RT01	Regenerative Thermal Oxidizer
SV6	Sterilization Chamber # 6	2006	RT01	Regenerative Thermal Oxidizer
SV7	Sterilization Chamber # 7*	Future	RT01	Regenerative Thermal Oxidizer
A1A/B	Aeration Room 1 – Primary and Secondary Cell	2006	RT01	Regenerative Thermal Oxidizer
A2A/B	Aeration Room 2 – Primary and Secondary Cell	2006	RT01	Regenerative Thermal Oxidizer
A3A/B	Aeration Room 3 – Primary and Secondary Cell	2006	RT01	Regenerative Thermal Oxidizer

Emission Units			Associated Control Devices	
Source Code	Description	Installation Date	Source Code	Description
A4A/B	Aeration Room 4 – Primary and Secondary Cell	2006	RT01	Regenerative Thermal Oxidizer
A5A/B	Aeration Room 5 – Primary and Secondary Cell	2006	RT01	Regenerative Thermal Oxidizer
A6A	Aeration Room 6	2006	RT01	Regenerative Thermal Oxidizer
A7A/B	Aeration Room 7 – Primary and Secondary Cell	~2009	RT01	Regenerative Thermal Oxidizer

Fugitive Emission Sources

Source Code	Description
STOR	Product Storage

Emissions Summary

Facility-Wide Emissions (in tons per year)

Pollutant	Potential Emissions (before modification)	Actual Emissions (before modification)	Potential Emissions (after modification)	Actual Emissions (after modification)
	TPY	TPY		
PM	1.86	1.86	1.86	1.86
NO _x	34.6	34.6	34.6	34.6
SO ₂	2.93	2.93	2.93	2.93
CO	18.19	18.19	18.19	18.19
VOC	1.36	1.36	1.36	1.36
Max. Individual HAP (Ethylene Oxide)	2.0	2.0	2.6	2.6
Total HAP	2.32	2.32	2.92	2.92

Regulatory Applicability

40 CFR 63 Subpart O – Ethylene Oxide Emission Standards for Sterilization Facilities.

Permit Conditions

Condition No. 2.1 requires BD to comply with 40 CFR 63 Subpart O.

Condition No. 2.2 requires BD to comply with 40 CFR 63 Subpart A, General Provisions.

Pursuant to 40 CFR 63.362(c), Condition No. 2.3 requires BD to reduce ethylene oxide emissions from the sterilizers by at least 99 percent.

Pursuant to 40 CFR 63.362(d), Condition No. 2.4 requires BD to reduce the ethylene oxide emissions vented from the aeration rooms to 1 part per million by volume (ppmv) or by 99 percent.

Pursuant to 40 CFR 63.362(b), Condition No. 2.5 requires BD to be in compliance with Condition Nos. 2.3 and 2.4 at all during sterilization operation but not during any malfunctions.

Pursuant to 40 CFR 63.360(g), Condition No. 2.6 requires BD to comply with the emission limitations as stated therein.

Pursuant to 40 CFR 63.363(b)(3) and 40 CFR 63.363(f), Condition No. 4.2 requires BD to operate the RTO at a temperature equal to or above the minimum temperature established during the most recent performance test but not lower than the minimum temperature recommended by the RTO manufacturer except during periods of startup or shutdown.

Pursuant to 40 CFR 63.364(c), Condition No. 5.1 requires BD to measure and record either the ethylene oxide concentration or to continuously monitor and record the oxidation temperature of the RTO. Note that monitoring is required only when the RTO is in operation.

Pursuant to 40 CFR 63.364(c), Condition No. 5.2 requires BD to install, calibrate, maintain, and operate a system to continuously monitor the oxidation temperature of the RTO and determine the average oxidation temperature.

Pursuant to 40 CFR 63.364(c)(4), Condition No. 5.3 requires BD to verify the accuracy of the temperature monitoring system twice each calendar year using a reference temperature monitor or an independent temperature measurement device.

Pursuant to 40 CFR 63.8(d) and (e), Condition No. 5.4 requires BD to develop and implement a continuous monitoring system (CMS) quality control program.

Condition No. 5.5 requires BD to ensure that any monitoring system installed is in continuous operation except during calibration checks, zero and span adjustments or periods of repairs.

Condition No. 5.6 requires BD to maintain a spare parts inventory for any monitoring system installed.

[Note that Condition Nos. 6.2 and 6.3 of Permit No. 3841-211-0021-S-03-0 have been deleted because the testing requirements have been completed.]

Pursuant to 40 CFR 63.7(b) and 63.9(e), Condition No. 6.2 requires BD to notify the Division of intent to conduct a performance test at least 60 days before the performance test.

Pursuant to 40 CFR 63.7(c)(4), Condition No. 6.3 requires BD to analyze performance audit samples during each performance test.

Pursuant to 40 CFR 63.7(d), Condition No. 6.4 requires BD to provide performance testing facilities and to ensure that performance tests are conducted based on representative normal operating conditions.

[Note that Condition Nos. 7.2 and 7.9 of Permit No. 3841-211-0021-S-03-0 have been deleted because Condition No. 7.2 is not applicable to synthetic minor sources and the notification requirement of Condition No. 7.9 has been completed.]

Condition No. 7.1 requires BD to maintain records of and duration of any startup, shutdown, and malfunction as well as any malfunction of the air pollution control equipment and continuous monitoring system or device and retain a record for at least five years after the date of any such event.

Condition No. 7.2 requires BD to maintain a file of all measurements required by the permit as stated therein.

Pursuant to 40 CFR 63.7(c)(2), Condition No. 7.3 requires BD to submit a site-specific test plan along with the notification of intent to conduct a performance test.

Pursuant to 40 CFR 63.7(g), 63.9(h), 63.10(d), and 63.366(a), Condition No. 7.4 requires BD to submit the results of a performance test and notification of compliance status within 60 days after the completion of the test.

Pursuant to 40 CFR 63.10, 63.366(a), and Table 1 of 40 CFR 63 Subpart O, Condition No. 7.5 requires BD to submit the reports stated therein.

Pursuant to 40 CFR 63.10(b)(1), Condition No. 7.6 requires BD to maintain files of all information required by the permit and by 40 CFR 63.

Pursuant to 40 CFR 63.10(b)(2) and (c), respectively, and Table 1 of 40 CFR 63 Subpart O, Condition No. 7.7 requires BD to maintain General records and CMS records.

Pursuant to 40 CFR 63.364(c), Condition No. 7.8 requires BD to compute and record a daily average oxidation temperature from the 15-minute or shorter period temperature values. Strip chart data are required to be converted to record a daily average oxidation temperature for each day any instantaneous temperature recording falls below the minimum temperature.

Pursuant to 40 CFR 63.10(e), Condition No. 7.9 requires BD to submit a semiannual report for any excess emissions, exceedances, and excursions as stated therein.

Condition No. 7.10 defines operational parameter deviations as stated therein.

Condition No. 8.3 revokes Air Quality Permit No. 3841-211-0021-S-03-0 in its entirety.

Summary & Recommendations

I recommend issuing this ownership change permit for this synthetic minor source. The source is assigned to the Northeast District for compliance purposes.