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ENVIRONMENTAL PROTECTION DIVISION

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NARRATIVE

TO: Stephen Damaske

FROM: Heather Brown

DATE: December 16, 2022

Facility Name:	**BD Madison**
AIRS No.:	21100021
Location:	Madison, GA (Morgan County)
Application #:	27352
Date of Application:	December 13, 2019; Revised February 12, 2021

Background Information

BD (Becton, Dickinson and Company) operates a facility that sterilizes medical equipment with ethylene oxide (EtO). The facility is located in Madison, Morgan County and operates under Air Quality Permit No. 3841-211-0021-S-04-0 issued on January 9, 2019. The facility is subject to 40 CFR 63 Subpart O – Ethylene Oxide Emission Standards from Sterilization Facilities.

Sterilization of medical equipment takes place in seven sterilization vessels. The packaged equipment is placed in the vessel and the chamber is charged with ethylene oxide. The gas permeates the packaging during the cycle. At the end of the cycle, the vessel is evacuated and backfilled with airwash. The evacuated gas is vented to the regenerative thermal oxidizer. The equipment pallets are then placed in one of seven primary aeration cells. In the aeration cells, the residual ethylene oxide dissipates and is evacuated to the regenerative thermal oxidizer. The pallets are then moved to the secondary aeration cells. Any residual ethylene oxide continues to dissipate and is vented to the regenerative thermal oxidizer.

Purpose of Application

Application No. 27352 was received on December 13, 2019. An update to the application was dated February 12, 2021. A public advisory was not required because the project resulted in a reduction in emissions. The additional controls discussed in this narrative were in full time operation on June 30, 2020.

The purpose of the application was the addition of controls for fugitive emissions from the existing operations. The controls for the sterilization vessel vents, the vessel backvents, and the aeration cells were not changed as a result of the project. The sources of fugitive emissions include the sterilization vessel rooms, the vessel to aeration transfer corridor, the EtO dispensing room, and the work in progress area, where sterilized product is stored. The sterilization vessel rooms, the vessel aeration transfer corridors, and the EtO dispensing rooms are controlled with a new dry bed system (SYS1) and the work in progress area is controlled with a separate new dry bed system (SYS2). The fugitive emissions are not required to be controlled under the current version of 40 CFR 63 Subpart O.

The permit has also been updated to include a control requirement for the sterilization vessel backvents, which are controlled by the regenerative thermal oxidizer. The backvents are not required to be controlled under the current version of 40 CFR 63 Subpart O.

Updated Equipment List

The equipment list has been updated to include the new control equipment.

Source Code	Description	Control Device	Description
SV1	Sterilization Vessel #1	RTO-1	Regenerative Thermal Oxidizer
SV2	Sterilization Vessel #2	RTO-1	Regenerative Thermal Oxidizer
SV3	Sterilization Vessel #3	RTO-1	Regenerative Thermal Oxidizer
SV4	Sterilization Vessel #4	RTO-1	Regenerative Thermal Oxidizer
SV5	Sterilization Vessel #5	RTO-1	Regenerative Thermal Oxidizer
SV6	Sterilization Vessel #6	RTO-1	Regenerative Thermal Oxidizer
SV7	Sterilization Vessel #7	RTO-1	Regenerative Thermal Oxidizer
BV1	Sterilization Vessel #1 Backvent	RTO-1	Regenerative Thermal Oxidizer
BV2	Sterilization Vessel #2 Backvent	RTO-1	Regenerative Thermal Oxidizer
BV3	Sterilization Vessel #3 Backvent	RTO-1	Regenerative Thermal Oxidizer
BV4	Sterilization Vessel #4 Backvent	RTO-1	Regenerative Thermal Oxidizer
BV5	Sterilization Vessel #5 Backvent	RTO-1	Regenerative Thermal Oxidizer
BV6	Sterilization Vessel #6 Backvent	RTO-1	Regenerative Thermal Oxidizer
BV7	Sterilization Vessel #7 Backvent	RTO-1	Regenerative Thermal Oxidizer
A1A/B	Aeration Room 1 – Primary and Secondary Cells	RTO-1	Regenerative Thermal Oxidizer
A2A/B	Aeration Room 2 – Primary and Secondary Cells	RTO-1	Regenerative Thermal Oxidizer
A3A/B	Aeration Room 3 – Primary and Secondary Cells	RTO-1	Regenerative Thermal Oxidizer
A4A/B	Aeration Room 4 – Primary and Secondary Cells	RTO-1	Regenerative Thermal Oxidizer
A5A/B	Aeration Room 5 – Primary and Secondary Cells	RTO-1	Regenerative Thermal Oxidizer
A6A	Aeration Room 6	RTO-1	Regenerative Thermal Oxidizer
A7A/B	Aeration Room 7 – Primary and Secondary Cells	RTO-1	Regenerative Thermal Oxidizer
VRM1	Vessel Room 1	SYS1	Dry Bed System 1
VRM2	Vessel Room 2	SYS1	Dry Bed System 1
VRM3	Vessel Room 3	SYS1	Dry Bed System 1
VRM4	Vessel Room 4	SYS1	Dry Bed System 1
VRM5	Vessel Room 5	SYS1	Dry Bed System 1
VRM6	Vessel Room 6	SYS1	Dry Bed System 1
VRM7	Vessel Room 7	SYS1	Dry Bed System 1
UCO1	Vessel to Aeration Transfer 1	SYS1	Dry Bed System 1
UCO2	Vessel to Aeration Transfer 2	SYS1	Dry Bed System 1
DRM1	EtO Dispensing 1	SYS1	Dry Bed System 1
DRM2	EtO Dispensing 2	SYS1	Dry Bed System 1
WIP1	Work in Progress Area	SYS2	Dry Bed System 2

Emissions Summary

Potential emissions of EtO from the source have been reduced as a result of the project. EtO is classified as a hazardous air pollutant (HAP) and a volatile organic compound (VOC). The calculation methods used to review the projects are summarized after the facility wide emission table.

Facility-Wide Emissions
(in pounds per year)

Pollutant	Emissions		
	Potential Emissions Before Mod.	Potential Emission After Mod.	Estimated Actual Emissions After Mod.
$PM/PM_{10}/PM_{2.5}$	0	0	0
NOx	0	0	0
SO_2	0	0	0
CO	0	0	0
VOC	8,822	6,029	426.0
Max. Individual HAP	8,822	6,029	426.0
Total HAP	8,822	6,029	426.0

Pre-Modification Calculations[1]

Potential emissions before the modification were estimated based on 588,160 pounds per year of EtO usage, 99.0% control of the sterilization vessel vacuum pumps, the aeration room vents, and the vessel backvents. The 99.0% control efficiency was based on the requirements specified in 40 CFR 63 Subpart O. The indoor air is uncontrolled for the purposes of these calculations.

The pre-modification EtO emissions were estimated as follows:

E = Usage * {[A * (1-.99)] + [B * (1-.99)] + [C * (1-.99)] + [D]}

Where:

E = Yearly emissions in pounds of EtO;
Usage = Yearly usage in pounds of EtO;
A = Predicted fraction vented through vessel vacuum pumps: 95%;
B = Predicted fraction vented through aeration: 4%;
C = Predicted fraction vented through backvents: 1%; and
D = Fraction assumed associated with workspace: 0.5%.

E = 588,160 * {[0.95 * (1-.99)] + [0.04* (1-.99)] + [0.01* (1-.99)] + [0.005]}
E = 8,822.4 pounds EtO per year (approximately 4.41 tons per year)

[1] The fractional breakdown in the pre-modification and post-modification calculations results in slightly more than 100% of the emissions being accounted for. US EPA used 0.05% in developing the original 40 CFR Part 63 Subpart O to account for the "D" fraction. This calculation was also used to estimate potential emissions from the Sterigenics U.S. LLC facility.

Post-Modification Calculations

E = Usage * {[A * (1-.99)] + [B * (1-.99)] + [C * (1-.99)] + [D * (1-.95)]}

Where:

E = Yearly emissions in pounds of EtO;
Usage = Yearly usage in pounds of EtO;
A = Predicted fraction vented through vessel vacuum pumps: 95%;
B = Predicted fraction vented through aeration: 4%;
C = Predicted fraction vented through backvents: 1%;
D = Fraction assumed associated with workspace: 0.5%. Estimated average control efficiency is 95%. An efficiency greater than 95%, including 99%, is achievable most of the time. However, if inlet concentrations are very low efficiency may decrease.

E = 588,160 * {[0.95 * (1-.99)] + [0.04 * (1-.99)] + [0.01 * (1-.99)] + [0.005 * (1-.95)]}
E = 6,028.6 pounds EtO per year (approximately 3.01 tons per year)

Estimated Post-Modification Actual Emissions

Please see Attachment E of the application for the complete actual emissions analysis.

Actual emissions were calculated based on site specific data such as:

- EtO usage per pallet of product;
- The percentage of EtO removed by the vessel vacuum pumps;
- Amount of EtO remaining in the product prior to entering aeration as based on laboratory testing;
- Aeration cell loading time and cycle time;
- RTO destruction efficiency of 99.7% for the aeration cells as determined during 2018 performance testing (40 CFR 63 Subpart O requires 99%);
- RTO destruction efficiency of 99.999% for the vessel pump vents based on 2018 performance testing (40 CFR 63 Subpart O requires 99%);
- Dry bed system efficiency of at least 95%; and
- Safety factors to account for variability in the process.

E = RTO + Dry Bed System 1 + Dry Bed System 2 + LDAR Components
E = 28.9 lbs + 17.6 lbs + 379.5 lbs + 0.047 lbs
E = 426.0 pounds EtO per year (approximately 0.21 tons per year)

Regulatory Applicability

BD Madison is subject to 40 CFR 63 Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities. The regulation requires the following:

- The facility must reduce emissions from each sterilization vessel vacuum pump by at least 99% in accordance with 40 CFR 63.362(a) and (c). BD is in compliance with this provision. The control equipment demonstrated an efficiency of 99.9995% during the 2018 testing.

- The facility must reduce emissions from each aeration room by at least 99% or to a maximum outlet concentration of 1 part per million by volume, whichever is less stringent in accordance with 40 CFR 63.362(a) and (d). BD is in compliance with this provision. The control equipment demonstrated an efficiency of 99.7% during the 2018 testing.

40 CFR 63 Subpart O does not require control of the backvents as specified in 40 CFR 63.362(a). BD currently controls the backvents and the new permit specifies a minimum control efficiency of 99% or 1 ppmv outlet concentration for consistency.

Testing and Montioring

Regenerative Thermal Oxidizer (RTO-1)
The RTO controls EtO emissions from the sterilization vessel pumps, the aeration cells, and the vessel backvents. The RTO has been tested and demonstrates compliance with the destruction efficiency required by regulation. The facility monitors temperature in order to determine proper operation of the control device. 40 CFR 63 Subpart O requires the facility to maintain and verify the accuracy of the temperature monitors. A performance test is required within 6 months of the issuance date of this permit.

Dry Bed Systems 1 and 2 (SYS1 and SYS2)
The dry beds are new systems used to control the indoor air as specified in the equipment list. The initial monitoring for the bed will be weekly bag samples at the bed outlets. If the sample indicates a concentration equal to or above 0.5 ppmv, the facility must replace the bed material. Performance testing is required within 6 months of the issuance date of this permit.

Continuous Emissions Monitoring Systems
The new permit requires the facility to install and operate CEMS for measuring and recording EtO emissions from each stack. The CEMS may subsume the monitoring for the RTO depending on future rulemaking. The GA EPD has the authority to allow the CEMS to be used as monitoring for the dry beds and will require the facility to do so once the monitors are in place.

Permit Conditions

Conditions 1.1 through 1.5 are general requirements that apply to all facilities.

Condition 2.1 is a new requirement that limits usage of EtO at the facility to 588,160 pounds per consecutive 12-month period.

Condition 2.2 states the emission reduction requirements apply at all times of facility operation. This GA EPD provision subsumes 40 CFR 63 Subpart O, which had an exception for malfunctions.

Conditions 2.3 and 2.4 require the facility to comply with 40 CFR 63 Subpart A – General Provisions and 40 CFR 63 Subpart O – Ethylene Oxide Emission Standards for Sterilization Facilities.

Condition 2.5 specifies the EtO control requirements for sterilization vessel vents under 40 CFR 63 Subpart O.

Condition 2.6 specifies the EtO control requirements for the aeration cell vents under 40 CFR 63 Subpart O.

Condition 2.7 requires the facility to control EtO emissions from the sterilization vessel backvents by at least 99% or to 1 ppm. These vents are not required to be controlled under 40 CFR 63 Subpart O. The backvents at BD are already controlled with the RTO. This enforceable requirement has been added to the permit.

Condition 3.1 is a standard fugitive emission requirement that applies to all sources.

Conditions 4.1 through 4.3 are standard air pollution control equipment requirements that apply to all sources.

Conditions 4.4 through 4.6 specify where each EtO vent must exhaust in order to meet the control requirements in Section 2.

Condition 4.7 and 4.8 specify to which new dry bed system each indoor air source should be routed.

Condition 5.1 is a standard monitoring condition that applies to all sources.

Conditions 5.2 through 5.5 specify how temperature must be monitored for the RTO and how the temperature monitor(s) must be maintained and verified. The language has been updated to include reference to the CEMS GA EPD is requiring within 12 months of issuance of the permit. The language has also been updated to state the temperature monitoring applies at all times in order to match the provisions of Condition 2.2.

Condition 5.6 requires the facility to conduct weekly sampling for the dry bed systems in order to ensure proper operation of the units. The sampling will be replaced with the CEMS once it is in place. The dry bed material must be replaced when monitoring results require it to be done as specified in the condition.

Condition 5.7 requires the facility to equip the stacks with EtO continuous emission monitoring systems, flow rate monitoring systems, and any other systems necessary to convert concentrations to mass emission rates. The deadline to install the CEMS is 12 months after the permit is issued, to allow the Permittee time to purchase, install, and set up the device(s).

Condition 5.8 requires the facility to submit a monitoring plan for the CEMS prior to installation. The plan is subject to review and approval by the Division. The plan will include accuracy and sensitivity levels to be approved by the Division based on expected commercially-available CEMS specifications (for example, a non-detect level of 10 ppb and an accuracy of 10 ppb). The plan will also include plans for conducting Relative Accuracy Test Audits (RATA).

Condition 5.9 requires the facility to operate in accordance with a Division-approved Work Practice Plan. The plan must include a monitoring protocol for the negative pressure system associated with the indoor air sources.

Condition 5.10 requires the facility to develop and implement a leak detection and repair program.

Condition 6.1 lists standard test requirements that apply to all sources.

Condition 6.2 through 6.4 require the facility to conduct performance testing, using the procedures specified in 40 CFR 63 Subpart O or other procedures approved by EPA and/or the Division on all emission exhausts. The facility is required to use the testing to establish the minimum operating temperature for the RTO. The conditions also require reporting of emissions in terms of a mass emission rate. These tests will be used to demonstrate compliance with the percent reduction requirements in Subpart O and will be used for emissions calculation purposes until the CEMS is installed.

Condition 6.5 requires the facility to conduct RATAs on the CEMS.

Conditions 7.1 and 7.2 are standard record keeping requirements that apply to all sources.

Condition 7.3 is a requirement of 40 CFR 63 Subpart O and requires the Permittee to keep records as specified in the rule and in 40 CFR 63 Subpart A.

Condition 7.4 specifies the deviations the facility must report. Reporting includes occurrences of RTO temperature deviations, occurrences of high dry bed outlet concentrations, and instances where dry bed material is not replaced as specified in the permit.

Condition 7.5 is a requirement of 40 CFR 63 Subpart O and requires the Permittee to submit deviation reports and continuous monitoring system performance reports.

Condition 7.6 requires the facility to submit a semiannual report (including the items in Condition 7.4) relating to any excess emissions, exceedances, and/or excursions, in addition to monitor malfunctions.

Conditions 7.7 requires the facility to maintain records of the amount of EtO used daily.

Conditions 7.8 and 7.9 require the facility to maintain records of EtO usage on a monthly and 12-month rolling basis. The records will be used to demonstrate compliance with the 588,160 pound per 12-consecutive month period limit. The conditions also require the Permittee to report when monthly usage exceeds 1/12th of the limit and if the 12-month rolling limit is exceeded.

Conditions 7.10 and 7.11 require the facility to calculate emissions of EtO from the source on a monthly and 12-month rolling basis. Until the CEMS is installed, emissions will be calculated using the equations in Attachment E of Application No. 27352, the most recently approved regenerative thermal oxidizer efficiencies, the emission rates (lb/hr) from the most recent dry bed system performance tests, the records of losses from any malfunctions, leaks, spills, etc., and Leak Detection and Repair components.

Condition 7.12 requires the Permittee to include the EtO usage and emissions in the semiannual report.

Condition 7.13 requires the facility to notify the Division of all unpermitted releases, in accordance with recent revisions to Georgia Code O.C.G.A. § 12-9-7(a).

Condition 7.14 prohibits the start-up of new sterilization cycles if performance testing at the RTO indicates non-compliance with the applicable control efficiency requirement.

Condition 8.1 is a standard requirement that applies to all sources.

Condition 8.2 requires the facility to pay annual fees.

Condition 8.3 revokes the permit previously issued to the source.

Toxic Impact Assessment

Application No. 27352 was an emission reduction project. A Toxic Impact Assessment is not required. The Permittee conducted modeling for the emission reduction project. Results of that modeling were reviewed by EPD. See the EPD Modeling Memorandum for more information.

Summary & Recommendations

A public advisory was not required for Application No. 27352 because the application resulted in a reduction in emissions from the source. The facility continues to be classified as a synthetic minor source and continues to comply with the provisions of 40 CFR 63 Subpart O. Compliance responsibility is maintained by the Stationary Source Compliance Program of the Air Protection Branch. I recommend the issuance of Air Quality Permit No. 3841-211-0021-S-05-0 to BD Madison for the emission reduction project as described in Application No. 27352.