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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 Monitoring

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.

PUBLIC NOTICE AND HEARING

A public notice was issued for the draft BD Covington and BD Madison permits on February 22, 2023. The Division simultaneously published the draft permits on the EPD website and announced a public hearing that was held via Zoom on March 27, 2023. Written comments were accepted through April 3, 2023. The hearing was held jointly for both BD Covington and BD Madison due to the similarity between the sources and applicable permit language. All comments have been considered as they apply to both draft permits.

Public Hearing Verbal Comments and EPD Responses

Stephen Damaske, Stationary Source Permitting Program Manager, opened the hearing with a short presentation of the BD sterilization process and the updates to the requirements established in the draft permits. The hearing session was then opened to accept verbal comments.

Verbal Comment 1

Mr. Greg Crist, Chief Advocacy Officer and Head of External Affairs for the Advanced Medical Technology Association (AdvaMed), read a prepared comment in support of the facility. The text of the comment was also provided by email and is included in the written comment section below.

EPD Response – Comments noted.

Verbal Comment 2

Mr. Boone Brothers, Sr. Manager EHS, UCC Business Unit, Beckton Dickinson and Company, spoke in support of the facility. Mr. Brothers also submitted written comments which are summarized in the written comment section below.

EPD Response – Comments noted.

Written Public Comments and EPD Responses

The deadline for written comments was April 3, 2023.

Written Comment 1

Mr. Greg Crist submitted a written version of the verbal comments he gave during the hearing. Please see "Verbal Comment 1" above. The comment was received by email on March 30, 2023:

> Thank you and I appreciate the time to comment today.
>
> My name is Greg Crist and I am here on behalf of AdvaMed, the Advanced Medical Technology Association.
>
> AdvaMed is the largest medical technology association, representing the innovators and manufacturers transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our more than 400 members range from small, emerging companies to large multinationals and include traditional device, diagnostic, and digital health technology companies.

Ethylene Oxide, or EtO, is one of the most common ways to sterilize medical devices, which is crucial for preventing infection in patients undergoing surgical procedures and other medical treatments. Hundreds of thousands of medical, hospital, and laboratory processes rely on EtO to sterilize devices and equipment to protect millions of patients from the real risks of infectious diseases caused by bacteria, viruses, and fungi. More specifically, EtO is used to sterilize approximately 50 percent of all medical devices – 20 billion – in the United States each year, including surgical kits, heart valves, and pacemakers, and is the only viable modality for many devices.

Other methods destroy or render these critical medical devices unusable. The appropriate sterilization method is determined during the concept and design phase of a device. Manufacturers opt to use the sterilization method for each device that meets design specifications, FDA requirements, patient safety, and the large-scale demand for devices, all without impacting device functionality.

Any disruption in the availability of sterile medical devices and supplies could lead to delays in patient care – an outcome disastrous to patient safety, the daily practice of medicine, and overall public health in the United States. Dr. Amanda Sivek of the ECRI Institute drives this home: "Currently, there are no validated industrial sterilization alternatives that could completely replace EtO sterilization, so additional closures of EtO processing facilities would have the potential to impair the U.S. healthcare system."

In closing, I'll note that both the U.S. Food and Drug Administration (FDA), which regulates medical device safety and effectiveness, including sterility assurance, and the Environmental Protection Agency (EPA), which regulates EtO emissions in the air, not only agree EtO is a critical medical device sterilization method, but that it cannot be replaced for certain medical devices.

Thank you again for the opportunity to comment today.

EPD Response – Comments noted.

Written Comment 2
Mr. Boone Brothers, Sr. Manager EHS, UCC Business Unit, Beckton Dickinson and Company, submitted written comments and draft permit markups on behalf of the facility via email on April 3, 2023. The complete comment letters and documents are available upon request.

A. Condition 7.14 Should Not Require BD to Obtain Written Approval From the Division Before Restarting Sterilization Operations, Where the Last Performance Test Shows Compliance

Condition 7.14 of the permit specifies what BD must do in the event that any performance test conducted in accordance with Section 6 of the permit "indicates non-compliance with the applicable control efficiency standard." First, BD must "notify the Division within 60 days." This is a reasonable requirement as it puts the Division on notice of potential issues at the facility that could lead to a noncompliance. Second, BD must "not initiate any new sterilization cycles in the Sterilization Vessels . . . after such notification without written approval from the Division." As set forth below, BD believes that this second requirement is unnecessary and disproportionate. If BD's control equipment is operating correctly, and the latest performance test of the equipment indicates compliance, BD should be free to operate its facilities pursuant to all permit requirements.

For example, after a failed performance test, BD (or the testing company) could determine that the test was flawed and likely produced inaccurate results. While the test technically "indicate[d] non-compliance," it created no reasonable justification for a facility shutdown if a subsequent test indicates compliance. Similarly, after a failed performance test, BD could inspect its equipment and quickly discover the cause of the non-compliance. Once the issue is remedied, there is no reason for the facility to remain shut down if a subsequent test indicates compliance. Nevertheless, Condition 7.14 does not specify when or under what circumstances the Division must provide its approval to restart, leaving it completely up to EPD's discretion. As a result, BD could plausibly be forced to stay shutdown for an extended period of time in connection with a minor or wholly-past issue simply because it could not reach anyone at the Division, the person available did not understand the situation, or the person available did not have authority to make a decision. In fact, BD could be required to remain shut down indefinitely for no reason at all. Any such shutdown would prevent BD from sterilizing the important medical devices needed by the customers in BD's supply chain, causing unnecessary strain on patients, healthcare providers, and the Company.

This result is disproportionate to any potential harm, since BD is already prohibited by permit Conditions 1.1, 2.2-2.7, 4.7-4.8, 5.6, and others from operating the facility except in compliance with applicable permit control equipment limits and standards. Therefore, we propose striking the following language:

7.14 In the event that any performance test conducted in accordance with Section 6 of this permit indicates non-compliance with the applicable control efficiency standard, the Permittee shall notify the Division within 60 days. In addition, the Permittee shall not initiate any new sterilization cycles in the Sterilization Vessels (Source Codes SV1, SV2, SV3, SV4, SV5) ~~after such notification without written approval from the Division~~, unless and until a subsequent performance test conducted in accordance with Section 6 of this permit shows compliance with the applicable control efficiency standard.

This change would also relieve the Division of direct involvement in the management of BD's business operations.

EPD Response – No changes have been made to the Covington/Madison permits as a result of this comment. A non-compliant performance test requires investigation by both the facility and the GA EPD. The language suggested by the commenter does not change the intent of the condition, which is that an investigation must take place prior to initiating new sterilization cycles whether or not additional performance testing is needed as part of the investigation.

B. Permit Monitoring Requirements Should be Consistent with Federal Requirements

As noted above, BD has 42 manufacturing facilities and over 30,000 employees across all 50 states, supplying hundreds of sterilized medical products to thousands of customers. This presents significant and constantly changing logistical challenges for the Company. Consequently, like many others in the regulated community who fully support robust environmental protections, BD is reliant on regulators to create workable standards that are as consistent as possible across jurisdictions. This is especially important where, as here, the State is regulating an essential area of interstate commerce (medical device sterilization) that the U.S. EPA already actively regulates. While the State may have some authority to regulate in such areas, it should be careful to ensure that any state-specific requirements do not force businesses to take actions, invest in equipment, or meet standards in competition with applicable federal standards. Such state requirements create unnecessary costs and inefficiencies that put businesses in a competitive disadvantage while achieving little or no environmental or health benefit for the people of the State.

BD believes that the Division's requirement to install continuous emissions monitoring system ("CEMS") at the site within 12 months is premature and should be modified for at least two reasons. First, the technology is not proven and may not be able to deliver the expected results in spite of BD's large investment of time and manpower. As U.S. EPA acknowledged, measuring EtO at the extremely low levels required in this permit presents significant technical challenges—even for single sample applications: "Legacy methods are no longer sensitive enough to measure at the concentrations needed to demonstrate compliance with some emission standards." There have recently been promising developments in this area, such as "Other Test Method 47" ("OTM-47") which utilizes a Cavity Ring-Down Spectroscopy ("CRDS") Instrument. However, these methods have no track record of supplying reliable and consistent test results. For example, in March 2023, EPA explicitly refused to endorse the validity of the OTM-47 for a CEMS application, stating that the Agency "does not have enough information onthe performance of this method to approve its use broadly at this time."

Second, in this case, we believe U.S. EPA is ultimately in the best position to craft the appropriate monitoring standard. U.S. EPA is the entity that conducted the ethylene oxide toxicology studies and air modeling that ultimately led to the installation of additional control equipment at the BD Covington and BD Madison facilities. Based on those actions, U.S. EPA has undertaken a review of Subpart O "to determine whether legal standards for EtO emissions to air can be further strengthened." This review included a "technology review" of Subpart O that will "examine developments in practices, processes and control technologies" that have emerged since 2006. The results of the technology review will be incorporated into an EPA action to revise Subpart O, which is expected imminently. In contrast, the Division has not conducted toxicology studies on ethylene oxide, does not have a full-time toxicologist to advise it on site-specific applications of EPA's standards, and has not conducted a comprehensive review of the efficacy and costs of

available monitoring systems. Nor has the Division formally solicited input from the regulated community and other stakeholders in this matter. With EPA's new rule expected shortly, it is unreasonable for the Division to impose new CEMS requirements on BD at this time.

It is also important to acknowledge that a short delay in installing CEMS would not reasonably be associated with new, potential health risks around the facilities. The BD Covington and BD Madison facilities currently ensure that residential receptors around the facility remain below the EPA-derived, 100-in-1,000,000 risk threshold using reliable methods other than a CEMS: control technologies, performance testing, LDAR, work practice standards, and modeling. As the Division is aware, recent EPA air monitoring of ethylene oxide has shown ethylene oxide levels nationwide at every receptor, often over EPA's reported safe levels even where the ethylene oxide could not plausibly be attributed to industrial sources. This generally comports with the Division's own testing. Thus, it is now clear that the ethylene oxide background levels are significant, making the CEMS data less useful for evaluating the impact of extremely small changes in ambient air concentrations on public health.

BD is not stating that it is categorically against installation of new monitoring equipment. Monitoring requirements are a normal part of air emissions control regimes and BD is ready to install whatever is required to ensure safe operations. As set out above, we simply believe that the CEMS requirement is premature based on the available technology. Therefore, we believe Condition 5.7 of the permit should be amended to allow U.S. EPA to publish its revision to Subpart O before the Division imposes a CEMS requirements on the BD Covington and Madison facilities. To this end, BD proposes the following edits to both permits:

5.7. Within twelve months of the issuance date of this permit, if US EPA amends 40 CFR 63 Subpart O to require the Permittee ~~shall~~ to install, calibrate, maintain, and operate a continuous emission monitoring system(s) (CEMS) to continuously monitor and record the pollutants in the following subparagraphs, the permittee shall satisfy the requirements of amended 40 CFR 63 Subpart O within the time allowed in the federal regulations. If US EPA does not amend 40 CFR 63, Subpart O to require CEMS within twelve months of the issuance date of this permit, the Permittee shall install, calibrate, maintain, and operate a CEMS in a period not to exceed eighteen additional months upon the written request of the Division. Each system shall meet the applicable requirements of the Division-approved monitoring plan specified in Condition 5.8.

These changes would make clear that BD must install CEMS if required by U.S. EPA in its upcoming rulemaking. However, if CEMS is not required by the Agency, the Division would have an opportunity to reevaluate its own position in light of U.S. EPA's technical studies and findings. This would allow the Division to act on the best available information, not an arbitrary deadline. If the Division were to conclude that CEMS was likely to provide a substantial benefit, it could require BD to install it at that time.

In either case, the provision should also be revised to reflect a reasonable timeline for conducting the engineering studies, finding qualified contractors, procuring the necessary equipment, and installing and commissioning the CEMS. Based on the novelty of the present application and the highly regulated nature of commercial sterilization operations, BD believes that this process would require approximately 18 months.

EPD Response – No changes have been made to the Covington/Madison permits as a result of this comment. The GA EPD is requiring sterilization facilities subject to control requirements under the current provisions of 40 CFR 63 Subpart O to install and operate CEMS within 12 months of issuance of the revised air quality permit. This requirement has been known by the applicable sources since the issuance of the Sterigenics U.S. LLC permit on January 6, 2022. The Division believes that sufficient time has and will be given by the new permit to procure and commission the CEMS.

C. EPD Should Clarify That Emissions Regulated by the Permit are Not a "Spill or Release"

BD understands its obligation under O.C.G.A. § 12-9-7 to report "any spill or release of ethylene oxide, regardless of the amount," and takes that obligation very seriously. As referenced in Condition 7.13, the term "spill or release" is defined by O.C.G.A. § 12-14-1(10) to mean "the emitting, releasing, [or] leaking . . . of any hazardous substance into the air . . . *except* . . . *as authorized by state or federal law or a permit from the division*." (Emphasis added). This exception is common sense. Among the primary purposes of securing an air permit from a State is to obtain conditional authorization to emit during facility's production processes pursuant to the permit's requirements. As explained by the U.S. Congressional Research Service: "The [Clean Air Act] permit states how much of which air pollutants a source is allowed to emit." This can include, among other things, primary emissions from the emission control system as well as incidental leaks that are routinely associated with the covered process equipment and controlled by an LDAR program. Without such authorizations, operations would be impossible.

In the pre-draft Covington and Madison permits, Condition 7.13 provides useful clarifying language regarding what constitutes an unauthorized release. Unfortunately, it does not provide similar clarifying language regarding what releases are authorized. BD believes such language is necessary in light of the extremely broad wording of O.C.G.A. § 12-9-7. Therefore, BD requests the following additional language:

7.13 Any spill or unpermitted release of ethylene oxide at the facility, regardless of the amount of the release, shall be reported to the Air Protection Branch by email (air.releases@dnr.ga.gov) within 24 hours of discovering such spill or release. As used in this condition, the term "spill or release" shall have the same meaning as set forth in the Georgia Code O.C.G.A. § 12-14-1. Emissions of ethylene oxide resulting from an operator error, a malfunction, or other failure of equipment at the facility that results in ethylene oxide not being routed through the air pollution control equipment prescribed in this permit are ~~is~~ an unauthorized release. Emissions of ethylene oxide resulting from operations of the facility addressed or otherwise controlled by limits, standards, or other requirements of this Air Quality Permit are an authorized release. The full report shall describe (1) the release, (2) its causes, (3) the estimated amount of ethylene oxide released, and (4) the steps taken to contain it and said report shall be submitted within 48 hours of the initial email notification.

We think this language will help reduce potential confusion regarding the scope of BD's authorized operations under the permit.

EPD Response – No changes have been made to the Covington/Madison permits as a result of this comment. The language of the condition already specifies that emissions routed through control equipment as required by the permit are not spills or unpermitted releases.

D. The Frequency of the Leak Detection and Repair ("LDAR") Program is Unreasonable

BD is fully committed to frequent and thorough leak detection and prevention at its Georgia facilities. Controlling fugitive emissions is an imperative for both environmental protection and industrial hygiene. In addition to using specialized LDAR equipment, both facilities are already equipped with internal detection and alarm systems that notify employees if fugitive emissions from an internal source reach certain thresholds.

Condition 5.10 of the permits require the Covington and Madison facilities to "check all outside components (valves, flanges, fittings, drums, etc.) for leaks with, at a minimum, weekly monitoring of all components." This level of frequency is unnecessary. As you know, both facilities have been successfully conducting an LDAR program since 2019. During that time, BD upgraded facility equipment to further minimize the risk of leaks. Over the past year, weekly readings from the LDAR program indicate that leaks from the facility are now very small and rare, fractions of a pound annually.

To provide perspective, as U.S. EPA explains in a 2014 LDAR guidance document, a typical refinery or chemical plant "can emit 600-700 tons per year of VOCs from leaking equipment, such as valves, connectors, pumps, sampling connections, compressors, pressure-relief devices, and open-ended lines." As the table below indicates, such facilities can have literally tens of thousands of components:

Table 3.2 – Equipment component counts at a typical refinery or chemical plant.

Component	Range	Average
Pumps	10 – 360	100
Valves	150 – 46,000	7,400
Connectors	600 – 60,000	12,000
Open-ended lines	1 – 1,600	560
Sampling connections	20 – 200	80
Pressure relief valves	5 – 360	90

Source: "Cost and Emission Reductions for Meeting Percent Leaker Requirements for HON Sources." Memorandum to Hazardous Organic NESHAP Residual Risk and Review of Technology Standard Rulemaking docket. Docket ID EPA-HQ-OAR-2005-0475-0105.

Huge quantities of materials move past these components under high pressures as they are pushed from one place to another for various purposes.

Here, the Covington facility is authorized to use approximately 261 tons per year of ethylene oxide gas (See Condition 2.1). The vast majority of the ethylene oxide will travel at relatively low pressures (drawn by industrial fans) through a short series of ductwork to an RTO, where it is destroyed at destruction efficiency of approximately 99.9% or greater. Much of the remaining ethylene oxide is pulled by fans through ductwork to two dry bed systems, where it is removed at a very high efficiency.

In light of BD's track record of very low LDAR emission and the nature of the operations at the BD Georgia facilities, the weekly LDAR requirement is unnecessary. We suspect it was carried-over from the 2019 consent order between BD and the State, which addressed facility operations in place before BD studied and characterized its fugitive emissions, installed its additional dry bed control system and negative pressure system to minimize fugitives, and optimized its LDAR program. Therefore, BD suggests the following change:

5.10 The Permittee shall develop, implement, and maintain an ethylene oxide Leak Detection and Repair Program. The program shall check all outside components (valves, flanges, fittings, drums, etc.) for leaks with, at a minimum, monthly~~weekly~~ monitoring of all components. The program, and any modifications to the program, shall be subject to review and approval by the Division. A copy of the program shall be submitted to the Division, in writing, no later than 60 days following the date of issuance of this permit.

As discussed above, we believe a monthly requirement is more than adequate.

EPD Response – No changes have been made to the Covington/Madison permits as a result of this comment. The Division believes that weekly LDAR checks are reasonable.

E. Additional Language Is Needed to Clarify the Scope of Permit Conditions Related to EtO Operations

BD believes a few provisions of the permit need to be clarified to apply more directly to the specific EtO emissions that they are intended to target and control. This clarity will minimize confusion for future staff at both Georgia EPD and BD as they apply the permit's terms.

1) Condition 2.2

Condition 2.2. of the Covington permit currently states:

2.2. The emission control requirements in Conditions 2.5 through 2.7 apply at all times of facility operation.

While Condition 2.2 refers broadly to "all times of facility operations," the Covington and Madison facilities have multiple, distinct operational functions, many of which do not involve the facility control equipment and do not create EtO emissions. For example, the facility accepts, unloads, and stores thousands of pallets of unsterilized medical devices which are placed in temporary storage before they are sterilized for use by BD customers.

The emission control requirements referenced in Condition 2.2 of the Covington and Madison permits, Conditions 2.5 – 2.7, refer to emission limits for specific emission sources: sterilization vessel vents (Source Codes SV1, SV2, SV3, SV4, SV5), aeration cell vents (Source Codes A1A, A2A, A3A, A4A, A5A, A1B, A2B, A3B, A4B, A5B), and sterilization vessel backvents (Source Codes BV1, BV2, BV3, BV4, BV5). These source codes cover BD's primary sterilization operations, where packaged and boxed medical products are placed into a sealed sterilization chamber, sterilized with EtO, and then aerated to remove residual gases. As permit Conditions 4.4 – 4.6 later clarify, BD complies with Conditions 2.5 – 2.7 "by routing the exhaust" from these sources "to the Regenerative

Thermal Oxidizer (Source Code RTO-1)." The RTO destroys the overwhelming majority of EtO before it enters the ambient air.

Logically, the emission control requirements in Conditions 2.5 through 2.7 should not apply when sterilization and aeration operations are not occurring, since the covered sources are not creating the emissions these conditions are intended to control. As such, Condition 2.2 should apply only during Covington and Madison "sterilization operations." Therefore, BD proposes the following change:

2.2. The emission control requirements in Conditions 2.5 through 2.7 apply at all times of ~~facility operation~~ "Sterilization Operations," i.e., the sterilization or aeration of product in Sterilization Vessels #1-5 (Source Codes SV1, SV2, SV3, SV4, SV5, BV1, BV2, BV3, BV4, BV5) and the aeration of sterilized product in Aeration Cells #1A-5B (Source Codes A1A, A2A, A3A, A4A, A5A, A1B, A2B, A3B, A4B, A5B) resulting in emissions to the ambient air.

We believe the precision of this provision, as edited, will allow for less confusion for plant operators and less need for interpretation by Georgia EPD down the road.

Defining the term "Sterilization Operation" will also bring clarity to the two other provisions discussed directly below.

2) Condition 5.1

Condition 5.1 of the permit is also overbroad, stating: "Any continuous monitoring system required by the Division and installed by the Permittee shall be in continuous operation and data recorded during *all periods of operation of the affected facility* except for continuous monitoring system breakdowns and repairs . . ." (Emphasis added). As it is written, any CEMS would need to be in operation and recording data during all periods of "operation of the affected facility," with an exception for "system breakdowns and repairs." The scope of the term "operation of the affected facility" is not delineated and the term could be applied to cover all areas of the facility, including loading docks and non-sterilized product storage. Such activities are not intended to be covered by a CEMS, as is clear from condition 5.7 the permit.

To clarify the intended scope of this provision, BD recommends the following language:

5.1 Any continuous monitoring system required by the Division and installed by the Permittee shall be in continuous operation and data recorded during all periods of ~~operations of the affected facility~~ Sterilization Operations (as defined in Conditions 2.2); product transfer operations in the Vessel Rooms (Source Codes VRM1, VRM2, VRM3, VRM4, VRM5) or the Vessel Aeration Transfer Corridor (Source Code NCO1); product storage and handling operations in the Work in Progress Area (Source Code WIP1); and EtO drum handling, connecting, and disconnecting operations in the EtO Dispensing Room (Source Code DRM1) except for continuous monitoring system breakdowns and repairs.

This change clarifies that CEMS is intended to monitor the effectiveness of the emission control equipment covering EtO operations, not the entirety of both facilities.

3) Condition 7.4(a)

Condition 7.4(a) would also benefit from a clarification delineating its scope. The provision addresses information that must be included in a required "semi-annual report," stating:

> 7.4 For each regenerative thermal oxidizer oxidation temperature measurement conducted in accordance with Condition 5.3.a, dry bed system sample in Condition 5.6, and the continuous emission monitoring system (CEMS) in Condition 5.7, the Permittee shall include the following information in the semiannual report required by Condition 7.6. [391-3-1-.02(6)(b)1.]
>
> a. For the Regenerative Thermal Oxidizer (Source Code RTO-1), any occurrence when the oxidation temperature is less than the minimum temperature established during performance testing and approved by the Division when using the Condition 5.3.a monitoring option. [40 CFR 63.363(b)(3)]
>
> * * *

Currently, the "any occurrence" language could be read to require reporting of RTO temperature measurements even if taken when no product is being sterilized. For example, after startup or between batches, an operator might observe a dip in RTO temperature. If there is no indication of system problems, the operator might take simple steps to increase the temperature to the appropriate level before commencing sterilization operations. In such case, there would be no need to require the facilities to generate and report special records, creating opportunities for reporting violations with no clear benefit to the Division or the public. Further, if the dip in temperature were related to a malfunction, the facilities are already required to maintain records under Condition 7.2.

Therefore, BD proposes the following edit:

> 7.4 For each regenerative thermal oxidizer oxidation temperature measurement . . .the Permittee shall include the following information in the semiannual report required by Condition 7.6. [391-3-1-.02(6)(b)1.]
>
> a. For the Regenerative Thermal Oxidizer (Source Code RTO-1), any occurrence during Sterilization Operations (as defined in Condition 2.2) when the oxidation temperature is less than the minimum temperature established during performance testing and approved by the Division when using the Condition 5.3.a monitoring option. [40 CFR 63.363(b)(3)]
> * * *

EPD Response – No changes have been made to the Covington/Madison permits as a result of these comments. The purpose of Condition 2.2 is to distinguish the language in Georgia's more stringent permits, which unlike the current version of 40 CFR 63 Subpart O, do not give compliance allowances for startup, shutdown, or malfunction. It should also be noted that sterilized product is on site at Covington/Madison and required to be controlled by the fugitive emissions control system. As such, for the purposes of Georgia's permit, "facility operation" is not limited to the use of the sterilization vessels or the aeration cells. Condition 5.1 is intended to be broad and is a standard requirement for synthetic minor sources. The site-specific provisions that apply to the facility are detailed in Conditions 5.2. through 5.10 of each permit. The Division believes that data collected in accordance with Condition 7.4.a is not a burdensome requirement.

F. Other Proposed Changes to the Permits

In addition, to the changes requested above, BD believes the following changes would further strengthen the permit.

4) Clarify the Location of Testing Required Under Conditions 6.1 and 6.2

Section 6 of the permit deals with performance testing of facility control equipment. Condition 6.1 states that the Permittee "shall cause to be conducted a performance test at any specified emission point when so directed by the Division." Condition 6.2 addresses the RTO, stating that "[w]ithin 6 months after the initial issuance date of this Permit, the Permittee shall conduct ethylene oxide performance testing of the sterilization vessel vents (Source Codes SV1, SV2, SV3, SV4, SV5), sterilization vessel backvents (Source Codes BV1, BV2, BV3, BV4, BV5) and aeration cell vents (Source Codes A1A, A2A, A3A, A4A, A5A, A1B, A2B, A3B, A4B, A5B) . . ."

These provision could arguably be read to indicate that performance testing should occur "at" the listed sources. However, as the BD facilities are configured, these sources are not emission points. All emissions from these sources are directed to the RTO before entering the ambient air. Therefore, we recommend the following two changes:

6.1. The Permittee shall cause to be conducted a performance test at any specified emission point (i.e. the RTO-1 outlet, the SYS1 outlet, or the SYS2 outlet) when so directed by the Division. The following provisions shall apply with regard to such tests:

* * *

6.2. Within 6 months after the initial issuance date of this Permit, the Permittee shall conduct ethylene oxide performance of the outlet for sterilization vessel vents (Source Codes SV1, SV2, SV3, SV4, SV5), sterilization vessel backvents (Source Codes BV1, BV2, BV3, BV4, BV5) and aeration cell vents (Source Codes A1A, A2A, A3A, A4A, A5A, A1B, A2B, A3B, A4B, A5B) according to . . .

These changes make clear that testing should occur where emissions from these sources leaves the facility, i.e., the RTO-1 outlet (or the SYS1 outlet or the SYS2 outlet, for provisions addressing the dry beds).

EPD Response – No changes have been made to the Covington/Madison permits as a result of these comments. Condition 6.1 is a general language that applies to all synthetic minor sources. It is not intended to be specific solely for the control devices listed by the commenter. For Condition 6.2, the language was written to prescribe testing while taking into account 40 CFR 63 Subpart O provisions, as well as provisions related to compliance with Georgia's more stringent permits. Specific test locations will be listed in the test plans to be approved by the Division.

5) Conditions 5.4 Should Allow the Facility to Utilize Data From CEMS, If Installed

As discussed above, BD does not believe that CEMS should be required to be installed at its Georgia facilities until U.S. EPA has been given the opportunity to address their efficacy in its Subpart O rulemaking. However, if the facility does install CEMS, BD believes that Condition 5.4 should be modified to reflect its functionality.

Condition 5.4 is an operational requirement that sets a baseline minimum operating temperature for the RTO, while allowing BD to lower the minimum temperature where performance testing shows that the facility can still meet emission requirements at the lower level. This allowance prevents the needless waste of natural gas and reduces unnecessary wear and tear on the RTO. The provision also includes a conservative backstop, preventing BD from lowering the temperature below the manufacturer's recommended minimum level, regardless of test results.

BD recommends the following change to clarify that, in addition to performance testing, consistent CEMS readings over a set period of time would also provide a sufficient basis for lowering the RTO minimum operating temperature:

5.4 The Permittee shall operate the Regenerative Thermal Oxidizer (Source Code RTO-1) at or above 1447 degrees Fahrenheit (or a new minimum oxidation temperature approved in writing by the Division). An operating parameter deviation is defined as any 24-hour average of the oxidation temperature for the Regenerative Thermal Oxidizer that is below 1447 degrees Fahrenheit (or a new minimum oxidation temperature approved in writing by the Division). The Permittee may establish a new minimum oxidation temperature based on performance testing or, if a CEMS monitor has been installed, confirmation by one month of CEMS monitoring data showing emissions levels consistently below the emission control requirements in Conditions 2.5 through 2.7 and that is at least equal to or higher than the recommended minimum oxidation temperature provided by the Regenerative Thermal Oxidizer manufacturer.

In light of the conservative backstop (the manufacturer's minimum recommended temperature), it is appropriate to allow BD to take steps to conserve fuel and preserve equipment using the CEMS. If the Division does not trust the accuracy of the CEMS, it should not mandate its installation at the facility.

EPD Response – No changes have been made to the Covington/Madison permits as a result of this comment. Condition 5.3.b of both permits includes provisions for the use of the CEMS in lieu of temperature monitoring.

6) Conditions 7.4(c) Should Incorporate Condition 5.9

As discussed above, Conditions 7.4 sets out the information that must be included in the semiannual "excess emissions, exceedances, and/or excursions" report required by Condition 7.6. Conditions 7.4(c) states, in pertinent part, that "For each . . . continuous emission monitoring system (CEMS) in Condition 5.7, the Permittee shall include . . . Any instance that negative pressure cannot be verified for the systems controlling indoor air *as specified in Conditions 4.7 and 4.8*." (Emphasis added). In fact, Conditions 4.7 and 4.8 describe the control equipment requirements for "indoor air," not negative pressure verification. Requirements for the negative pressure system are set out in condition 5.9, which states, in pertinent part, that the permittee must "develop, implement, and maintain a Work Practice Plan for the indoor air systems," "operate the facility in accordance with the plan," and conduct "monitoring . . . at least once per day." Therefore, Condition 7.4(c) should be amended to state:

c. Any instance that negative pressure cannot be verified for the systems controlling indoor air as specified in Conditions 5.9~~4.7 and 4.8~~.

This clarifies that the process for verifying negative pressure system operation is set forth in Condition 5.9, not Conditions 4.7 and 4.8.

EPD Response – No changes have been made to the Covington/Madison permits as a result of this comment. Reference to Conditions 4.7 and 4.8 was intentional.

7) Conditions 7.8 Is Unnecessary

Condition 7.8 requires BD "to calculate the total ethylene oxide usage for each calendar month" and "notify the Division in writing if ethylene oxide usage exceeds 43,541 pounds during any calendar month" (i.e., one-twelfth on the yearly limit: 522,500 pounds/12). BD believe that this Condition 7.8 is not needed.

BD is already required to maintain records of daily ethylene oxide usage under Condition 7.7. Further, Condition 7.9 requires BD "to determine the 12-month rolling total ethylene oxide usage for each calendar month" and to "notify the Division in writing if ethylene oxide usage exceeds 522,500 pounds during any consecutive 12-month period." While there is a permit cap on total usage of ethylene oxide "during any consecutive 12-month period" (Condition 2.1) that corresponds to Condition 7.9, there is not a monthly limit corresponding to Condition 7.8. A monthly limit is unnecessary where, as here, maximum monthly emission rates are already indirectly controlled by a 12-month "rolling" average.

We therefore recommend striking Condition 7.8 in its entirety and amending Condition 7.9 as follows:

7.9 The Permittee shall use the ethylene oxide records specified in ~~calculations required by~~ Condition 7.7~~7.8~~ to determine the 12-month rolling total ethylene oxide usage for each calendar month. The Permittee shall notify the Division in writing if ethylene oxide usage exceeds 522,500 pounds during any consecutive 12-month period. . . .

These small modifications to Condition 7.9 are necessary to fill gaps when Condition 7.8 is struck.

EPD Response – No changes have been made to the Covington/Madison permits as a result of this comment. Monthly calculations and reporting are standard requirements for synthetic minor sources where there is a numerical usage limit on a 12-month basis. The records are used to prevent unexpected exceedances of the 12-month limit. The monthly value is a tracking mechanism, not a limit.

G. Proposed Changes to the Permit Narratives

In addition to the requested changes to the proposed permits, BD also requests the following changes to the permit narratives. These requests apply to both permits, unless explicitly limited.

1) The Permit Narrative Should Explain That the Pre- and Post-Modification Calculations Are Not Based on BD's Facility-Specific Assumptions

Potential to emit "PTE" is a site-specific value which depends on facility design, processes, control equipment, and other factors. The Pre- and Post-Modification calculations in the permit narratives are based on a general assignment of fractional values to each regulated emission point. Vessel vacuum pumps are estimated to constitute 95% of EtO emissions; aeration vents are estimated to constitute 4% of EtO emissions; backvents are estimated to constitute 1% of EtO emissions. Similarly, "workspace" fugitive emissions were estimated to be 0.5% of total yearly EtO usage. In fact, according to Footnote 1 of the permit narratives, these same fractions were used to estimate PTE for a Sterigenics facility in Georgia, despite significant differences between the Sterigenics and BD facilities in design, sterilization equipment, sterilization processes, and control equipment.

As a result, BD requests the following changes:

Pre-Modification Calculations
Potential emissions before the modification were estimated based on 522,500 pounds per year of EtO usage, 99.0% control of the sterilization vessel vacuum pumps, the aeration cell 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. A preset fraction of the yearly EtO usage was assigned to each of the three regulated emission points (sterilization vessel vents, aeration cell vents, and sterilization vessel backvents). Fractions are based on generic assumptions about sterilization operations and are not facility-specific. The workspace EtO percentage is also not facility-specific. Yearly EtO emissions totals would likely change if the site-specific numbers in Attachment E of the Covington permit application were utilized.

These edits clarify that the PTE calculation is not based on the facility-specific information BD provided in the permit applications (Attachment E) for each facility, and that use of facility-specific values could change the calculated PTE.

EPD Response – No changes have been made to the Covington/Madison permits as a result of this comment. While the sterilization process is generally the same across sources, the Division acknowledges that each individual source will have specific conditions that impact actual emissions. The calculations presented in the first two columns of the emissions table for Sterigenics, BD Covington, and BD Madison use fractions historically referenced by 40 CFR 63 Subpart O, the minimum control efficiency allowed by the subpart, and control efficiencies established by the Division for non-Subpart O regulated emissions. This allows the reader to make a generalized, consistent comparison across sterilization sources in Georgia. The Division also included site specific actual emission totals for each facility, which take into account site specific operational information, control devices, and control efficiencies demonstrated during performance testing. The actual emission totals were taken from Attachment E as provided by BD for each facility.

2) EPD Should Correct the Transcription Errors in the "Estimated Post-Modification Actual Emissions"

The third set of calculations in the Emission Summaries section for each permit narrative are labeled "Estimated Post-Modification Actual Emissions," and are presented as "actual" emissions. They reference Attachment E of the applications as their source. However, both narratives incorporate values from Page 1 of 2 of Attachment E, in which BD calculated the facilities "PTE." Estimated "actual" emissions for each facility are found on Page 2 of 2 of each Attachment E.

BD therefore requests that the corresponding "actual" values from each Attachment E be transcribed into the permit narrative. For example, in the Covington permit, the following change would be made:

Estimated Post-Modification Actual Emissions

Please see Page 2 of 2 of 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 2019 performance testing (40 CFR 63 Subpart O requires 99%);
- RTO destruction efficiency of 99.9925% for the vessel pump vents as determined during 2019 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 = ~~59.4~~ 44.4 lbs + ~~16.6~~ 13.7 lbs + ~~330.2~~ 304.7 lbs + ~~0.024~~ 0.018 lbs
E = ~~406.2~~ 304.7 pounds EtO per year (approximately ~~0.203~~ 0.152 tons per year)

EPD Response – No changes have been made to the Covington/Madison permits as a result of this comment. The Division agrees that page 1 of 2 of Attachment E for each application was used for the actual emission calculation. While the calculation uses the permitted EtO usage limit, it also uses the actual control efficiencies demonstrated at the facility, such as 99.9925% RTO destruction efficiency for the vessel pump vents rather than the 99% allowed by regulation in the example above. Further, it is understood that, in general, actual emissions will be less if less EtO is used over the year. Because future actual usage cannot be predicted, it is consistent to use the permitted usage limit for the purposes of the emissions table.

3) EPD Should Correct the Pre- and Post-Modification Calculations for the Covington Permit Narrative

In the Emission Summary section of the Covington permit narrative only, BD identified an error in the Pre- and Post-Modification calculations that should be corrected. The "yearly usage in pounds of EtO" is initially listed as 522,500, as set out in BD's permit application and Condition 2.1 of the pre-draft permit. That number was incorrectly transcribed into the emissions calculations as 552,500 pounds. As a result, the yearly Pre-Modification emissions of EtO was calculated to be 8,287.5 pounds (4.14 tons), instead of 7,837.5 pounds (3.92 tons).

The Post-Modification emissions calculation correctly lists the yearly usage as 522,500 pounds. However, the calculation was apparently carried out using 552,500 pounds. As a result, the yearly emissions were calculated as 5,663.1 pounds (2.83 tons), instead of 5,355.6 pounds (2.68 tons).

We request that these calculations be corrected both in the Facility-Wide Emission table and in the Pre-Modification Calculations and Post-Modification Calculations sections of the Covington permit narrative.

EPD Response – The Division agrees with the comment. The corrected information for the Covington narrative was addressed in the 3841-217-00021-S-05-0 Narrative Addendum. There were no changes made to the permits.

4) EPD Should Correct the Updated Equipment List for the Madison Permit Narrative

In the Updated Equipment List for the Madison permit narrative only, BD identified two small errors in the Source Code column. The source code for "Aeration Room 5, Primary and Secondary Cells" was labeled A6A, rather than A5A/B. And the source code for "Aeration Room 6" was labeled A6A/B, rather than A6A. Both of these changes are noted in our markup of the pre-draft Madison permit narrative.

EPD Response – The table in the publicly noticed narrative is correct. No changes have been made to the permits as a result of this comment.