

PERMIT NO. 3841-211-0021-S-05-0
ISSUANCE DATE:



GEORGIA

DEPARTMENT OF NATURAL RESOURCES

ENVIRONMENTAL PROTECTION DIVISION

Air Quality Permit

In accordance with the provisions of the Georgia Air Quality Act, O.C.G.A. Section 12-9-1, et seq and the Rules, Chapter 391-3-1, adopted pursuant to and in effect under that Act,

Facility Name: BD Madison
Facility Address: 1211 Mary Magnan Boulevard
Madison, Georgia 30650 Morgan County
Mailing Address: 8195 Industrial Boulevard
Covington, Georgia 30014
Facility AIRS Number: 04-13-211-00021

is issued a Permit for the following:

Operation of an ethylene oxide sterilization facility, including the construction and operation of two indoor air capture systems with Dry Bed Systems (Source Codes SYS1 and SYS2). The Permit also requires the installation and operation of ethylene oxide continuous emission monitoring systems. This Permit is issued for the purpose of establishing practically enforceable emission limitations such that the facility will not be considered a major source with respect to Title V of the Clean Air Act Amendments of 1990.

This Permit is conditioned upon compliance with all provisions of The Georgia Air Quality Act, O.C.G.A. Section 12-9-1, et seq, the Rules, Chapter 391-3-1, adopted and in effect under that Act, or any other condition of this Permit.

This Permit may be subject to revocation, suspension, modification or amendment by the Director for cause including evidence of noncompliance with any of the above; or for any misrepresentation made in Application No. 27352 dated December 13, 2019 and revised on February 12, 2021; any other applications upon which this Permit is based; supporting data entered therein or attached thereto; or any subsequent submittals or supporting data; or for any alterations affecting the emissions from this source.

This Permit is further subject to and conditioned upon the terms, conditions, limitations, standards, or schedules contained in or specified on the attached 12 pages.



PRE-DRAFT

Richard E. Dunn, Director
Environmental Protection Division

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EQUIPMENT LIST

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

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1. General Requirements

- 1.1 At all times, including periods of startup, shutdown, and malfunction, the Permittee shall maintain and operate this source, including associated air pollution control equipment, in a manner consistent with good air pollution control practice for minimizing emissions. Determination of whether acceptable operating and maintenance procedures are being used will be based on information available to the Division which may include, but is not limited to, monitoring results, opacity observations, review of operating and maintenance procedures, and inspection or surveillance of the source.
- 1.2 The Permittee shall not build, erect, install or use any article, machine, equipment or process the use of which conceals an emission which would otherwise constitute a violation of an applicable emission standard. Such concealment includes, but is not limited to, the use of gaseous diluents to achieve compliance with an opacity standard or with a standard that is based on the concentration of a pollutant in the gases discharged into the atmosphere.
- 1.3 The Permittee shall submit a Georgia Air Quality Permit application to the Division prior to the commencement of any modification, as defined in 391-3-1-.01(pp), which may result in air pollution and which is not exempt under 391-3-1-.03(6). Such application shall be submitted sufficiently in advance of any critical date involved to allow adequate time for review, discussion, or revision of plans, if necessary. The application shall include, but not be limited to, information describing the precise nature of the change, modifications to any emission control system, production capacity and pollutant emission rates of the plant before and after the change, and the anticipated completion date of the change.
- 1.4 Unless otherwise specified, all records required to be maintained by this Permit shall be recorded in a permanent form suitable for inspection and submission to the Division and shall be retained for at least five (5) years following the date of entry.
- 1.5 In cases where conditions of this Permit conflict with each other for any particular source or operation, the most stringent condition shall prevail.

2. Allowable Emissions

Sterilant Usage Limit

- 2.1 The Permittee shall not utilize more than 588,160 pounds of ethylene oxide, as introduced into the sterilization vessels (Source Codes SV1, SV2, SV3, SV4, SV5, SV6, SV7), during any consecutive 12-month period.
[Georgia Rule 391-3-1-.02(2)(a)(3)(ii)]
- 2.2 The emission control requirements in Conditions 2.5 through 2.7 apply at all times of facility operation.
[Georgia Rule 391-3-1-.02(2)(a)(3)(ii); 40 CFR 63 Subpart O Subsumed]

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40 CFR 63 Subpart O

- 2.3 The Permittee shall comply with all applicable provisions of the National Emission Standard for Hazardous Air Pollutants (NESHAP) as found in 40 CFR 63 Subpart O – “Ethylene Oxide Emission Standards for Sterilization Facilities,” for the operation of the ethylene oxide sterilization equipment.
[40 CFR 63 Subpart O; 40 CFR 63.360]
- 2.4 The Permittee shall comply with all applicable provisions of the National Emission Standard for Hazardous Air Pollutants (NESHAP) as found in 40 CFR 63 Subpart A – “General Provisions.”
[40 CFR 63 Subpart A]
- 2.5 The Permittee shall reduce ethylene oxide emissions to the atmosphere from each sterilization vessel vent (Source Codes SV1, SV2, SV3, SV4, SV5, SV6, SV7) by at least 99%.
[40 CFR 63 Subpart O; 40 CFR 63.362(c)]
- 2.6 The Permittee shall reduce ethylene oxide emissions to the atmosphere from the aeration cell vents (Source Codes A1A/B, A2A/B, A3A/B, A4A/B, A5A/B, A6A, A7A/B) to a maximum concentration of 1 part per million, volume basis (ppmv), or by at least 99%, whichever is less stringent.
[40 CFR 63 Subpart O; 40 CFR 63.362(d)]

Sterilization Vessel Backvents

- 2.7 The Permittee shall reduce ethylene oxide emissions to the atmosphere from each sterilization vessel backvent (Source Codes BV1, BV2, BV3, BV4, BV5, BV6, BV7) to a maximum concentration of 1 part per million, volume basis (ppmv) or by at least 99%, whichever is less stringent.
[Georgia Rule 391-3-1-.03]

3. Fugitive Emissions

- 3.1 The Permittee shall take all reasonable precautions with any operation, process, handling, transportation, or storage facilities to prevent fugitive emissions of air contaminants.

4. Process & Control Equipment

- 4.1 Routine maintenance shall be performed on all air pollution control equipment. Maintenance records shall be recorded in a permanent form suitable and available for inspection by the Division. The records shall be retained for at least five (5) years following the date of such maintenance.
- 4.2 A spare parts inventory for control equipment shall be maintained by the Permittee.

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- 4.3 Malfunctioning components of air pollution control systems shall be repaired as expeditiously as possible.

Sterilization Vessel Vents

- 4.4 The Permittee shall comply with Condition 2.5 by routing the exhaust from each sterilization vessel vacuum pump (Source Codes SV1, SV2, SV3, SV4, SV5, SV6, SV7) to the Regenerative Thermal Oxidizer (Source Code RTO-1).
[Georgia Rule 391-3-1-.02(2)(a)(3)(ii); 40 CFR 63 Subpart O; 40 CFR 63.362(c)]

Aeration Cell Vents

- 4.5 The Permittee shall comply with Condition 2.6 by routing the exhaust from the aeration cell vents (Source Codes A1A/B, A2A/B, A3A/B, A4A/B, A5A/B, A6A, A7A/B) to the Regenerative Thermal Oxidizer (Source Code RTO-1).
[Georgia Rule 391-3-1-.02(2)(a)(3)(ii); 40 CFR 63 Subpart O; 40 CFR 63.362(d)]

Sterilization Vessel Backvents

- 4.6 The Permittee shall comply with Condition 2.7 by routing the exhaust from each sterilization vessel backvent (Source Codes BV1, BV2, BV3, BV4, BV5, BV6, BV7) to the Regenerative Thermal Oxidizer (Source Code RTO-1).
[Georgia Rule 391-3-1-.02(2)(a)(3)(ii)]

Indoor Air

- 4.7 The Permittee shall route the air from the Vessel Rooms (Source Codes VRM1, VRM2, VRM3, VRM4, VRM5, VRM6, VRM7), Vessel to Aeration Transfer 1 (Source Code UCO1), Vessel to Aeration Transfer 2 (Source Code UCO2), EtO Dispensing 1 (Source Code DRM1), and EtO Dispensing 2 (Source Code DRM2) to Dry Bed System 1 (Source Code SYS1).
[Georgia Rule 391-3-1-.02(2)(a)(3)(ii)]
- 4.8 The Permittee shall route the air from the Work in Progress Area (Source Code WIP1) to Dry Bed System 2 (Source Code SYS2).
[Georgia Rule 391-3-1-.02(2)(a)(3)(ii)]

5. Monitoring

- 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 operation of the affected facility except for continuous monitoring system breakdowns and repairs. Monitoring system response, relating only to calibration checks and zero and span adjustments, shall be measured and recorded during such periods. Maintenance or repair shall be conducted in the most expedient manner to minimize the period during which the system is out of service.
[391-3-1-.02(6)(b)1.]

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- 5.2 The Permittee shall install, calibrate, maintain, and operate a system to continuously monitor and record the oxidation temperature as determined from the average reading of the three combustion chamber temperature sensors on the Regenerative Thermal Oxidizer (RTO-1). Monitoring is required only when Regenerative Thermal Oxidizer RTO-1 is operated. The temperature monitor shall be accurate within ± 5.6 degrees Celsius (± 10 degrees Fahrenheit). Where such performance specification(s) exist, each system shall meet the applicable performance specification(s) of the Division's monitoring requirements.
[40 CFR 63 Subpart O; 40 CFR 63.364(c)]
- 5.3 For sterilization facilities complying with 40 CFR 63.363 through use of a regenerative thermal oxidizer (Source Code RTO-1), the Permittee shall either:
[40 CFR 63.364(c) and 391-3-1-.02(6)(b)1.]
- a. Continuously monitor and record the oxidation temperature using the temperature monitor(s) described in Condition 5.2. Monitoring is required only when the Regenerative Thermal Oxidizer is operated. The data acquisition system for the temperature monitors required by Condition 5.2 shall compute and record a daily average oxidation temperature from the 15-minute or shorter period temperature values. Strip chart data shall be converted to record a daily average oxidation temperature for each day any instantaneous temperature recording falls below the minimum temperature.
- b. In lieu of compliance with subparagraph a. of this Condition, the Permittee may use the ethylene oxide CEMS required by Condition 5.7, provided that US EPA approves in writing the CEMS- related conditions in this permit as acceptable monitoring for 40 CFR 63 Subpart O.
- 5.4 The Permittee shall operate the Regenerative Thermal Oxidizer (Source Code RTO-1) at or above 1449.2 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 1449.2 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 and that is at least equal to or higher than the recommended minimum oxidation temperature provided by the Regenerative Thermal Oxidizer manufacturer.
[Georgia Rule 391-3-1-.02(2)(a)(3)(ii); 40 CFR 63 Subpart O; 40 CFR 63.363(b)(3); 40 CFR 63.363(f) Subsumed]
- 5.5 The Permittee shall verify the accuracy of the temperature monitor required by Condition 5.2 twice each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested. As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards). Replacing the temperature monitor with a new manufacturer-calibrated probe also meets these requirements.
[40 CFR 63 Subpart O; 40 CFR 63.364(c)(4)]

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- 5.6 The Permittee shall maintain and operate the Dry Bed Systems 1 and 2 (Source Codes SYS1 and SYS2) as follows:
[391-3-1-.02(6)(b)1.]
- a. Once per week the Permittee shall collect and record the concentration of a 15-minute ethylene oxide bag sample from the outlet of each dry bed system. If any 2 consecutive weekly ethylene oxide outlet concentration measurements equal or exceed 0.5 ppmv, the Permittee shall replace the dry bed material within 30 days. The dates of dry bed material replacement shall be recorded and kept in a form suitable for inspection or submission to the Division.
 - b. When the Permittee is sampling in accordance with this Condition, the ethylene oxide concentration shall be recorded within 3 hours of the sampling event. These records shall be kept in a form suitable for inspection or submission to the Division.
 - c. Upon successful installation and initial operation of the ethylene oxide CEMS required by Condition 5.7, in lieu of compliance with paragraphs a. and b. above, the Permittee shall use the CEMS to determine outlet concentration on a ppm basis. If any 30-day rolling average ethylene oxide concentration equals or exceeds 0.2 ppmv, the Permittee shall replace the dry bed material within 30 days, unless an extension is granted in writing by the Division. The dates of dry bed material replacement shall be recorded and kept in a form suitable for inspection or submission to the Division.
- 5.7 Within twelve months of the issuance date of this permit, the Permittee shall install, calibrate, maintain, and operate a continuous emission monitoring system(s) (CEMS) to continuously monitor and record the pollutants in the following subparagraphs. Each system shall meet the applicable requirements of the Division-approved monitoring plan specified in Condition 5.8.
[391-3-1-.02(6)(b)1)]
- a. Ethylene oxide from the outlet of the Regenerative Thermal Oxidizer (Source Code RTO-1);
 - b. Ethylene oxide from the outlet of Dry Bed System 1 (Source Code SYS1); and
 - c. Ethylene oxide from the outlet of Dry Bed System 2 (Source Code SYS2).

The sources specified in this condition shall be equipped with continuous flow rate monitoring systems, and any other necessary systems, for converting CEMS concentration data to a mass flow rate, and shall be operated in accordance with the approved monitoring plan.

- 5.8 No later than sixty (60) days prior to the operation of the CEMS required by Condition 5.7, the Permittee shall submit to the Division, in writing, an ethylene oxide CEMS monitoring plan. The plan, and any modifications to said plan, shall be subject to the review and approval by the Division.
[391-3-1-.02(6)(b)1.]

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- 5.9 The Permittee shall develop, implement, and maintain a Work Practice Plan for the indoor air systems. The Permittee shall operate the facility in accordance with the plan, which shall include a monitoring protocol to demonstrate proper operation of the negative pressure system used to control emissions from the Vessel Rooms (Source Codes VRM1, VRM2, VRM3, VRM4, VRM5, VRM6, VRM7), Vessel to Aeration Transfer 1 (Source Code UCO1), Vessel to Aeration Transfer 2 (Source Code UCO2), EtO Dispensing 1 (Source Code DRM1), EtO Dispensing 2 (Source Code DRM2), and Work in Progress Area (Source Code WIP1). Negative pressure system monitoring shall be conducted at least once per day. All records necessary to demonstrate compliance with the Work Practice Plan shall be kept in a form suitable for inspection or submission to the Division.
[391-3-1-.02(6)(b)1.]

The Permittee shall submit a Work Practice Plan within 60 days after issuance of this permit to ensure consistency with the requirements of this permit. The plan must also include a protocol to minimize ethylene oxide emissions from on-site trucks containing sterilized product.
[391-3-1-.02(6)(b)1.]

- 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, 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.
[391-3-1-.02(6)(b)1.]

6. Performance Testing

- 6.1 The Permittee shall cause to be conducted a performance test at any specified emission point when so directed by the Division. The following provisions shall apply with regard to such tests:
- a. All tests shall be conducted and data reduced in accordance with applicable procedures and methods specified in the Division's Procedures for Testing and Monitoring Sources of Air Pollutants.
 - b. All test results shall be submitted to the Division within sixty (60) days of the completion of testing.
 - c. The Permittee shall provide the Division thirty (30) days prior written notice of the date of any performance test(s) to afford the Division the opportunity to witness and/or audit the test, and shall provide with the notification a test plan in accordance with Division guidelines.

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- d. All monitoring systems and/or monitoring devices required by the Division shall be installed, calibrated and operational prior to conducting any performance test(s). For any performance test, the Permittee shall, using the monitoring systems and/or monitoring devices, acquire data during each performance test run. All monitoring system and/or monitoring device data acquired during the performance testing shall be submitted with the performance test results.
- 6.2 Within 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, SV6, SV7), sterilization vessel backvents (Source Codes BV1, BV2, BV3, BV4, BV5, BV6, BV7) and aeration cell vents (Source Codes A1A/B, A2A/B, A3A/B, A4A/B, A5A/B, A6A, A7A/B) according to the procedures listed in 40 CFR 63.7 according to the applicability in Table 1 of 40 CFR 63.360, the procedures listed in 40 CFR 63.363, and the test methods listed in 40 CFR 63.365, or test methods approved by EPA and/or the Division. The test shall be used to establish the minimum oxidation temperature for the Regenerative Thermal Oxidizer (Source Code RTO-1). The test report shall list the control efficiency of the Regenerative Thermal Oxidizer and the final exhaust mass emission rate of ethylene oxide. [Georgia Rule 391-3-1-.02(2)(a)(3)(ii); 40 CFR 63 Subpart O; 40 CFR 63.363 and 63.365]
- 6.3 Within 6 months after the initial issuance date of this permit, the Permittee shall conduct ethylene oxide performance testing of Dry Bed System 1 (Source Code SYS1), according to the test methods approved by EPA and/or the Division. The test report shall list the final exhaust mass emission rate of ethylene oxide and the control efficiency of the dry bed system. [Georgia Rule 391-3-1-.02(2)(a)(3)(ii)]
- 6.4 Within 6 months after the initial issuance date of this permit, the Permittee shall conduct ethylene oxide performance testing of Dry Bed System 2 (Source Code SYS2), according to the test methods approved by EPA and/or the Division. The test report shall list the final exhaust mass emission rate of ethylene oxide and the control efficiency of the dry bed system. [Georgia Rule 391-3-1-.02(2)(a)(3)(ii)]
- 6.5 The Permittee shall conduct Relative Accuracy Test Audits (RATA) on the CEMS at a frequency of no less than every 12 months after initial installation and calibration of the CEMS. The results of the RATA shall be submitted to the Division in accordance with Condition 6.1.b.

7. Notification, Reporting and Record Keeping Requirements

- 7.1 The Permittee shall maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, any malfunction of the air pollution control equipment or any periods during which a continuous monitoring system or monitoring device is inoperative. The Permittee shall retain these records for a period of at least five (5) years after the date of any such startup, shutdown, or malfunction. [391-3-1-.02(6)(b)1.]

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- 7.2 The Permittee shall maintain a file of all measurements, including continuous monitoring system, monitoring device, and performance testing measurements; all continuous monitoring system performance evaluations; all continuous monitoring system or monitoring device calibration checks; adjustments and maintenance performed on these systems or devices; and all other information required by this Permit. The information shall be recorded in a permanent form suitable and available for inspection and shall be retained for at least five (5) years following the date of such measurements, maintenance, reports, and records.
[391-3-1-.02(6)(b)1.]
- 7.3 The Permittee shall maintain general records and continuous monitoring system (CMS) records as specified by 40 CFR 63.10(b)(2) and (c), respectively, and Table 1 of 40 CFR 63 Subpart O. [40 CFR 63 Subpart O; 40 CFR 63.367(a)]
- 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)]
 - b. For Dry Bed System 1 or 2 (Source Codes SYS1 and SYS2), any 2 consecutive measurements per Condition 5.6.a equal to or greater than 0.5 ppmv.
 - c. Any instance that negative pressure cannot be verified for the systems controlling indoor air as specified in Conditions 4.7 and 4.8.
 - d. For Dry Bed System 1 or 2 (Source Codes SYS1 and SYS2), any instance when a bed system is not replaced in accordance with Condition 5.6.
- 7.5 In accordance with 40 CFR 63.10, 63.366(a), and Table 1 of 40 CFR 63 Subpart O, the Permittee shall submit the following reports:
[40 CFR 63 Subpart O; 40 CFR 63.366(a)]
- a. Deviation reports; and
 - b. Continuous Monitoring System performance and summary reports.

Contents and submittal dates for Deviation and Continuous Monitoring System Performance Reports shall be as specified in 40 CFR 63.366(a)(3).

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- 7.6 The Permittee shall submit a written report containing any excess emissions, exceedances, and/or excursions as described in this permit and any monitor malfunctions for each semiannual period ending June 30 and December 31 of each year. All reports shall be postmarked by July 30 and January 30, respectively. In the event that there have not been any excess emissions, exceedances, excursions or malfunctions during a reporting period, the report should so state. Otherwise, the contents of each report shall be as specified by the Division's **Procedures for Testing and Monitoring Sources of Air Pollutants** and shall contain the following:
[391-3-1-.02(6)(b)1.; 40 CFR 63.10(e)]
- a. A summary report of excess emissions, exceedances and excursions, and monitor downtime, in accordance with Section 1.5(c) and (d) of the above referenced document, including any failure to follow required work practice procedures.
 - b. Total process operating time during each reporting period.
 - c. The magnitude of all excess emissions, exceedances and excursions computed in accordance with the applicable definitions as determined by the Director, and any conversion factors used, and the date and time of the commencement and completion of each time period of occurrence.
 - d. Specific identification of each period of such excess emissions, exceedances, and excursion that occur during startups, shutdowns, or malfunctions of the affected facility. Include the nature and cause of any malfunction (if known), the corrective action taken or preventative measures adopted.
 - e. The date and time identifying each period during which any required monitoring system or device was inoperative (including periods of malfunction) except for zero and span checks, and the nature of the repairs, adjustments, or replacement. When the monitoring system or device has not been inoperative, repaired, or adjusted, such information shall be stated in the report.
 - f. Certification by a Responsible Official that, based on information and belief formed after reasonable inquiry, the statements and information in the report are true, accurate, and complete.
- 7.7 The Permittee shall maintain records of the amount (in pounds) of ethylene oxide introduced into the sterilization vessels (Source Codes SV1, SV2, SV3, SV4, SV5, SV6, SV7) each day. The Permittee shall maintain these records on site at all times in a format suitable and available for inspection by or submittal to the Division on request.
[391-3-1-.02(6)(b)1.]

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7.8 The Permittee shall use the ethylene oxide records specified in Condition 7.7 to calculate the total ethylene oxide usage for each calendar month. All demonstration calculations shall be kept as part of the records required in this Condition. The Permittee shall notify the Division in writing if ethylene oxide usage exceeds 49,013 pounds during any calendar month. This notification shall be postmarked by the fifteenth day of the following month and shall include an explanation of how the Permittee intends to maintain compliance with the limit in Condition 2.1. The Permittee shall maintain these records on site at all times in a format suitable and available for inspection by or submittal to the Division on request.

[391-3-1-.02(6)(b)1.]

7.9 The Permittee shall use the calculations required by Condition 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 588,160 pounds during any consecutive 12-month period. This notification shall be postmarked by the fifteenth day of the following month and shall include an explanation of how the Permittee intends to attain compliance with the limit in Condition 2.1. The Permittee shall maintain these records on site at all times in a format suitable and available for inspection by or submittal to the Division on request.

[391-3-1-.02(6)(b)1.]

7.10 The Permittee shall calculate monthly ethylene oxide emissions using the CEMS data recorded in accordance with Condition 5.7.* Total emissions shall also include losses due to any malfunction, leaks, spills, etc. and Leak Detection and Repair Program components. All data needed to calculate emissions, and the calculations themselves, shall be kept as part of the monthly records. The Permittee shall maintain these records on site at all times in a format suitable and available for inspection by or submittal to the Division on request.

[391-3-1-.02(6)(b)1.]

*Prior to the installation and operation of the CEMS, the Permittee shall calculate the monthly ethylene oxide emissions using the usage records from Conditions 7.7 and 7.8, 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. All emission factors, efficiencies, emission rates, and calculations shall be kept as part of the monthly records, readily available for inspection or submittal.

[391-3-1-.02(6)(b)1.]

7.11 The Permittee shall use the calculations required by Condition 7.10 to determine the 12-month rolling total ethylene oxide emissions for each calendar month. The Permittee shall maintain these records on site at all times in a format suitable and available for inspection by or submittal to the Division on request.

[391-3-1-.02(6)(b)1.]

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7.12 The Permittee shall include the following information in the semiannual report required by Condition 7.6.

[391-3-1-.02(6)(b)1.]

- a. Total pounds of ethylene oxide usage for each month in the reporting period and the 12-month rolling total of ethylene oxide usage for each month in the reporting period, as calculated in accordance with Conditions 7.8 and 7.9.
- b. Total pounds of ethylene oxide emitted from the facility for each month in the reporting period and the 12-month rolling total of ethylene oxide emissions for each month in the reporting period, as calculated in accordance with Condition 7.10 and 7.11.

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 is a 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.

[Georgia Code O.C.G.A. § 12-9-7(a) and Georgia Rule 391-3-1-.02(2)(a)(3)(ii)]

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, SV6, SV7) after such notification without written approval from the Division.

[Georgia Rule 391-3-1-.02(2)(a)(3)(ii)]

8. Special Conditions

8.1 At any time that the Division determines that additional control of emissions from the facility may reasonably be needed to provide for the continued protection of public health, safety and welfare, the Division reserves the right to amend the provisions of this Permit pursuant to the Division's authority as established in the Georgia Air Quality Act and the rules adopted pursuant to that Act.

8.2 The Permittee shall calculate and pay an annual Permit fee to the Division. The amount of the fee shall be determined each year in accordance with the “Procedures for Calculating Air Permit Application & Annual Permit Fees.”

8.3 All Georgia Air Quality Permits previously issued to this facility, including Air Quality Permit No. 3841-211-0021-S-04-0 and its amendments, are hereby revoked in their entirety.