



Air Protection Branch

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

Compliance Monitoring Report

1. General Information

Date of Inspection: December 12, 2017
Date of Report Completed: December 20, 2017
Compliance Monitoring Category: Unannounced Inspection
Inspector Name: Sherry Waldron *[Signature]*
Reviewing Manager: Michael Odom *[Signature]*

2. Facility Information

Facility Name: KPR U.S., LLC d/b/a Kendall Patient Recovery U.S., LLC
Facility AIRS No.: 245-00109
Facility Location: 1430 Marvin Griffin Road
Augusta, Georgia 30913 (Richmond County)
Facility Mailing Address: P.O. Box 430
Augusta, Georgia 30913
Facility Contact: Terrial Campbell
EH&S Manager
706-771-2209
terrial.s.campbell@medtronic.com
CMS Designation: Synthetic Minor Source

Air Quality Permit No. 3842-245-0109-S-05-0

Effective Date: September 27, 2017

Issued for the operation of an ethylene oxide sterilization and wound care product facility. 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.

Permit(s) can be accessed at epd.georgia.gov/air

3. Inspection Summary / Recommended Actions:

The facility was operating in compliance with Air Quality Permit No. 3842-245-0109-S-05-0 at the time of the inspection.

4. Previous Enforcement Actions and Inspections:

There have been no enforcement actions at this facility during the previous five years. The most recent inspection was conducted on December 2, 2015. See attached Full Compliance Evaluation (FCE) Report for details.

5. Complaint Investigations since last Full Compliance Evaluation:

There have been no complaints received for this facility. See Complaint Tracking System (CTS) for further details.

6. Applicable Requirements, Description of Regulated Emission Units, and Inspection Determinations:

Emission Units		Corresponding Permit Conditions	Air Pollution Control Devices		Inspection	
ID No.	Description		ID No.	Description	Evaluated During Inspection?	Inspection Determination
SA	EtO Sterilization Chamber A	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.4, 2.5, 3.1, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 5.1, 5.2, 5.7, 5.8, 6.1, 6.2, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.13, 8.1, 8.2	RA CO	Recovery System A Catalytic Oxidizer [†]	Yes	In compliance
SB	EtO Sterilization Chamber B	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.4, 2.5, 3.1, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 5.1, 5.2, 5.7, 5.8, 6.1, 6.3, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.13, 8.1, 8.2	RB CO	Recovery System B Catalytic Oxidizer [†]	Yes	In compliance
FE1	Ethylene Oxide Sterilization Fugitive Emissions	1.1, 1.2, 1.3, 1.4, 1.5, 2.1, 2.2, 2.3, 2.4, 2.5, 3.1, 4.2, 4.4, 4.5, 4.6, 5.7, 5.8, 7.1, 7.2, 7.3, 7.5, 7.7, 7.8	None	None	Yes	In compliance
B2	31.5 mmBTU/hr Industrial Boiler 1989	1.1, 1.2, 1.3, 1.4, 1.5, 2.6, 2.7, 2.8, 2.9, 2.10, 2.12, 3.1, 4.4, 5.3, 5.4,, 5.5, 5.6, 6.1, 7.1, 7.2, 7.3, 7.8, 7.9, 7.10, 7.11, 7.12	None	Boiler	Yes	In compliance
B3	25.9 mmBTU/hr Clayton Boiler 2009	1.1, 1.2, 1.3, 1.4, 1.5, 2.6, 2.7, 2.8, 2.9, 2.11, 2.12, 2.16, 3.1, 4.4, 5.3, 5.4, 5.6, 6.1, 7.1, 7.2, 7.3, 7.8, 7.9, 7.10, 7.11, 7.14	None	Boiler	Yes	In compliance

Emission Units		Corresponding Permit Conditions	Air Pollution Control Devices		Inspection	
ID No.	Description		ID No.	Description	Evaluated During Inspection?	Inspection Determination
B4	25.9 mmBTU/hr Clayton Boiler 2009	1.1, 1.2, 1.3, 1.4, 1.5, 2.6, 2.7, 2.8, 2.9, 2.11, 2.12, 2.16, 3.1, 4.4, 5.3, 5.4, 5.6, 6.1, 7.1, 7.2, 7.3, 7.8, 7.9, 7.10, 7.11, 7.14	None	Boiler	Yes	In compliance
C2	Alcohol Prep Pad Machine	1.1, 1.2, 1.3, 1.4, 1.5, 3.1	N/a	N/a	Yes	In compliance
C3 through C6, C9, C11, and C18 through C21	Alcohol Prep Pad Machines	1.1, 1.2, 1.3, 1.4, 1.5, 3.1	N/a	N/a	Yes	In compliance
C24	Alcohol Prep Pad Machine	1.1, 1.2, 1.3, 1.4, 1.5, 3.1	N/a	N/a	Yes	In compliance
C25 and L1	Alcohol Prep Pad Machines	1.1, 1.2, 1.3, 1.4, 1.5, 3.1	N/a	N/a	Yes	In compliance
I2	Isopropyl Alcohol 5,000 gal tank	1.1, 1.2, 1.3, 1.4, 1.5, 3.1	N/a	N/a	Yes	In compliance
I3	Isopropyl Alcohol 8,000 gal tank	1.1, 1.2, 1.3, 1.4, 1.5, 3.1	N/a	N/a	Yes	In compliance

7. Compliance Monitoring Activities – Details not included in table above:

- a. Describe any deviation from compliance noted during the inspection listed on Table 6: None.
- b. Describe any compliance assistance provided during inspection: None.
- c. Describe any action taken by the facility to come back into compliance during the inspection: N/A
- d. Deviations noted during the inspection, not previously listed. Include equipment ID or equipment description and condition number: None identified.

8. Additional Permit Requirements:

- a. Periodic Reports:
Submitted as required. See attached Full Compliance Evaluation (FCE) Report for details.
- b. Permit Fees:
Paid as required. See attached Full Compliance Evaluation (FCE) Report for details.

- c. Permit Renewal and Expiration:
Not Applicable.
- d. For any overall emission/production/usage limit:

Table 8.d.		
Permit Condition	Permit Limit	Actual
2.1	Limit fuel oil combusted to 2,000,000 gallons combined during any consecutive 12-month period.	No fuel oil has been combusted in 2+ years.
2.2, 2.3, 2.4, 2.5	Meet requirements of Ethylene Oxide Emission Standards for Sterilization Facilities. Reduce emissions from each Sterilization Vent (SA and SB) by 99%. The emissions limit applies during sterilization operation, but not during periods of malfunction.	Last testing demonstrated compliance with EO standards. Chamber A tested on 11/23/09. Conducted on 1/23/09. 0.34 ppm 99.7% 309° F bed temperature Chamber B tested on 12/3/10. 0.77 ppm 99.9996% 319° F bed temperature
2.6, 2.7, 2.8	Limit fuel oil to 0.5% sulfur or less in Boilers B2, B3 and B4.	No fuel oil has been combusted in 2+ years.
2.9, 2.10	Limit opacity from Boilers B2, B3 and B4 to 20%.	No opacity was observed from these units. Units B2 and B4 were operating at the time of the inspection.
2.11	Limit particulate emissions to the limits of Rule (d).	Nothing was observed that would indicate noncompliance with these limits.
2.12	Comply with 40 CFR 63 Subpart JJJJJ for Boilers B2, B3, and B4.	The boilers meet the definition of gas-fired boilers and do not have any ongoing compliance requirements for this regulation.

9. Attachments:

- a. Inspection Observations:
See attachment
- b. Performance Tests:
See attachment
- c. Full Compliance Evaluation (FCE) Report:
See attachment

Attachment: Inspection Observations

Fugitive Emissions

Permit Condition	Permit Limit	Observation
3.1	Minimize fugitive emissions.	No fugitive emissions were observed during the inspection.

Process & Control Equipment

Permit Condition	Permit Limit	Observation
4.1	Conduct routine maintenance as needed. Maintain maintenance records.	Maintenance is scheduled on Maximo. There are monthly, quarterly, semiannual and annual preventative maintenance checks for the thermal oxidizers and monitoring devices associated with these control devices.
4.2	A spare parts inventory for control equipment shall be maintained	The spare parts inventory was e-mailed after the inspection; a copy of this is attached.
4.3	Repair malfunctioning components of air pollution control systems expeditiously.	All records reviewed indicated compliance with this requirement.
4.4	Operate the catalytic oxidizer (CO) at or above 300 degrees Fahrenheit, on a daily average, except during periods of startup, shutdown, or malfunction. An operating parameter deviation is defined as any daily average temperature that is below 300 degrees Fahrenheit.	Printouts of daily records were reviewed. No deviations were noted, except when power outages occurred or PMs were scheduled. Power outages cause the vents to be directed to the vent tank and is not vented to the atmosphere. PMs are scheduled when the process is down.
4.5	Once every 5 years, replace the catalyst bed in the catalytic oxidizer with new catalyst material.	Last catalyst bed replacement was November 28, 2013. The facility has already requested bids for the next replacement.

Monitoring

Permit Condition	Monitoring Requirement	Observation
5.1	Operate all monitoring systems or devices in continuous operation except during calibration checks, zero and span adjustments or periods of repair. Conduct maintenance or repair in an expedient manner.	All records reviewed indicated compliance with these requirements.
5.2	Maintain a spare part inventory for any monitoring system installed. Keep a list suitable for inspection.	The spare parts inventory was emailed after the inspection; a printout is attached.
5.3	Inspect each boiler annually and follow the boiler manufacturer's maintenance procedures to ensure that serviceable components are well maintained. Records of the maintenance performed on the boilers and the maintenance procedures shall be maintained for 5 years.	The boilers are inspected annually. No fuel oil has been burned in a couple of years. All records appeared to be maintained as required.
5.4	Maintain a system to continuously monitor and record the oxidation temperature at the outlet of the catalyst bed for the Catalytic Oxidizer (CO). The temperature monitor shall be accurate within ± 5.6 degrees Celsius (± 10 degrees Fahrenheit). Monitoring is required only when the oxidation unit is operated.	These records were extensively reviewed and appeared complete.
5.5	Verify the accuracy of the temperature monitor twice each calendar year.	These records were emailed after the inspection; a printout of these maintenance checks is attached.
5.6	Maintain a natural gas and fuel oil consumption meters on each boiler. In lieu of installing fuel meters, record the total amounts of natural gas and fuel oil delivered to the facility each calendar month.	A sample of the weekly report used to comply with this requirement is attached.
5.7	Verify fuel oil shipments meet permit limits through supplier certifications.	No fuel oil shipments in 2+ years.
5.8	Comply with the site-specific monitoring plan for the operation of the Industrial Boiler (B2).	This is applicable only when burning fuel oil; not applicable at this time.

Performance Testing

Permit Condition	Testing Requirement	Observation
6.1	Conduct performance test as directed by the Division.	None required.

Notification, Reporting and Record Keeping

Permit Condition	Permit Limit	Observation
7.1	Maintain records of any startup, shutdown, or malfunction, any malfunction of the air pollution control equipment or any periods during which a continuous monitoring system or monitoring device is inoperative. Retain these records for a period of five years.	An operating log record all such incidents. This appeared complete and corresponded to reports.
7.3	Maintain records of all measurements, all CMS performance evaluations, all calibration checks, adjustments and maintenance, for five years.	All records requested were available, except for those forwarded after the inspection. These were maintained by a maintenance person who was out for the day.
7.4	Retain the following records regarding fuel fired in any boiler: <ol style="list-style-type: none"> Shipping receipts for distillate fuel oil fired in each boiler. Confirmation of fuel oil sulfur content. Quantity of distillate fuel oil burned monthly in each boiler. Quantity of natural gas burned monthly in each boiler. As an alternative, maintain monthly records 	No fuel oil combusted recently.
7.5	Calculate monthly totals and 12-month totals of the amount of fuel oil fired. A new 12-month total shall be calculated for each calendar month.	No fuel oil combusted in 2+ years.
7.6	Compute and record a daily average oxidation temperature from the 15-minute or shorter period temperature values. Convert strip chart data to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature	The facility monitors temperature as required. Four thermocouples are in use: two on each line, thus ensuring redundancy.

7.7	Maintain records of the work practice requirements in Condition 4.5.	The facility has changed out the catalyst bed at the frequency required.
7.8	Maintain general records and CMS records as required by Subpart O.	All records appeared to be maintained as required.
7.9	Submit the following reports as per Subpart O: a. Deviation reports; and b. Continuous Monitoring System performance and summary reports	Reports are submitted as required. Information reviewed during the inspection was consistent with reports.
7.10	Submit semiannual reports documenting all deviations and corrective actions taken.	Semi-annual reports include all deviations and summaries.
7.11	Submit a semiannual report by January 30 and July 30 of each year, documenting fuel oil purchases and the firing of oil in any boiler. Include a certified statement signed by the Permittee that the records of fuel oil supplier certifications submitted represent all of the fuel oil fired in the boilers during the reporting period. Include the 12-month rolling total, in gallons, of the amount of fuel oil burned at the facility for each month in the reporting period. If no oil is burned, the report shall so state.	Reports have been submitted as required.
7.12	Implement and maintain a written site-specific monitoring plan for opacity of emissions from the Industrial Boiler (B2), including procedures and criteria for establishing and monitoring specific parameters for the boiler that are indicative of compliance with the opacity standard	Not inspected, as this was obtained in previous inspections. In addition, the plan only applies during fuel oil combustion.

Mr. Terrial Campbell, EH &S Manager, assisted me during the inspection, as well as Mr. Mark Legarda, Sterilization Manager. Each thermal oxidizer was operating above the required minimum temperature. Four thermocouples, two for each oxidizer, all read 329°F and above, well above the minimum. The facility was in full production. Mr. Campbell indicated the facility employed approximately 550 employees and operated three shifts, 24/7. All records reviewed were readily available except for a couple that were maintained by a maintenance employee that was not there that day. These included the semiannual thermocouple calibrations and the spare parts inventory. However, monthly and quarterly records were reviewed that indicated that routine maintenance is conducted, and calibrations for other sensors (flow, pressure, oxygen) were with these records. To save time, I requested that these records be forwarded to me via email. The records were later emailed and printouts are attached.

Housekeeping throughout the facility was good. No fugitive emissions were observed. Two of the three boilers were operating and exhibited no opacity, burning natural gas.

Attachment: Performance Tests

Previous test results

Source Tested	Pollutant	Date of Test	Required Testing Frequency	Limit	Actual	Percent of Allowable
Sterilization Chamber A	EtO	November 23, 2009	Upon startup	99% DRE	99.7% DRE	N/A
Sterilization Chamber B	EtO	December 3, 2010	Upon startup	99% DRE	99.7% DRE	N/A



GEORGIA

DEPARTMENT OF NATURAL RESOURCES

Richard E. Dunn, Director

Air Protection Branch

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

ENVIRONMENTAL PROTECTION DIVISION

Full Compliance Evaluation Report

**KPR U.S., LLC d/b/a Kendall Patient Recovery U.S.,
LLC, Augusta**

245-00109

Facility description: Surgical, Healthcare Products

1430 Marvin Griffin Rd
Augusta, GA 30906-3851

Richmond County
Lat: 33.396, Long: -81.981

Operating status: Operational
Classification: Synthetic minor
CMS status: SM
SIC code: 3842
NAICS code: 339113
Air Programs: SIP, NSPS, MACT
Classifications: None

Full Compliance Evaluation

FCE Year: 2018

FCE tracking number: 9201

Reviewed by: Waldron, Sherry

Date completed: 20-Dec-2017

On-site inspection conducted

Comments: N/A

Supporting compliance data for December 20, 2016 through December 20, 2017

Inspections

<u>Tracking #</u>	<u>Date</u>	<u>Inspector</u>	<u>Reason for inspection</u>	<u>Operating</u>	<u>Compliance status</u>
71098	12-Dec-2017	Waldron, Sherry	Planned Unannounced	Yes	Compliant

RMP Inspections

None

Annual Compliance Certifications

None

Reports

<u>Tracking #</u>	<u>Report period</u>	<u>Date received</u>	<u>Reviewer</u>	<u>Deviations reported</u>
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69300 First Semiannual 31-Jul-2017 Waldron, Sherry No
1-Jan-2017 – 30-Jun-2017

Comments: It appeared that all information required was reported, but the summary report form required by the PTM was requested to be submitted.

66307 Fourth Quarter 6-Feb-2017 Odom, Michael No
1-Oct-2016 – 31-Dec-2016

Comments: Quarterly fuel oil report required by Condition 18. Postmarked 5 days after the deadline. No further action.

66303 Second Semiannual 30-Jan-2017 Odom, Michael No
1-Jul-2016 – 31-Dec-2016

Comments: Semiannual report required by Condition 7.8.

Notifications

None

Source Tests

None

Fees Data

<u>Fee year</u>	<u>Invoiced amount</u>	<u>Amount paid</u>	<u>Balance</u>	<u>Status</u>
2012	\$3,200.00	\$3,200.00	\$0	Paid in Full
2013	\$3,200.00	\$3,200.00	\$0	Paid in Full
2014	\$3,200.00	\$3,200.00	\$0	Paid in Full
2015	\$3,553.60	\$3,553.60	\$0	Paid in Full
2016	\$3,200.00	\$3,200.00	\$0	Paid in Full

Five-Year History of Enforcement Actions

None