

  
Linda D. Hays, Clerk  
Newton County, Georgia

IN THE SUPERIOR COURT OF NEWTON COUNTY  
STATE OF GEORGIA

RICHARD E. DUNN, DIRECTOR,  
ENVIRONMENTAL PROTECTION  
DIVISION, GEORGIA DEPARTMENT OF  
NATURAL RESOURCES,

Plaintiff,

v.

BECTON, DICKINSON and COMPANY,

Defendant.

CIVIL ACTION FILE NO.

SUCV2019002219

**FIRST AMENDMENT TO CONSENT ORDER**

Plaintiff Richard E. Dunn, Director, Environmental Protection Division, Georgia Department of Natural Resources (“EPD”) and Defendant Becton, Dickinson and Company (“BD”) (the “Parties”) file this First Amendment to the Consent Order entered on October 28, 2019, (“Consent Order”) as follows:

**WHEREAS**, in the Consent Order entered by this Court, BD agreed to cease certain activities, conduct additional testing, submit additional engineering and regulatory documentation, implement process verification processes and procedures, and complete numerous activities by dates certain related to the medical device sterilization process, emissions and activities at the BD Covington and Madison, Georgia plants and at other storage locations in Covington;

**WHEREAS**, over the past two months, BD has, with oversight by EPD, collected significant environmental information related to the medical device sterilization process, and the Parties are collecting additional air quality and related information and other information and scientific data related to the understanding of air quality in the Covington and Madison areas;

**WHEREAS**, BD has made significant progress in completing the requirements under the Consent Order;

**WHEREAS**, on December 15, 2019, BD submitted the “Estimation of Fugitive Ethylene Oxide Emissions Report,” to EPD indicating, based on sampling data and engineering estimates, emissions from the Global Distribution Center (GDC) located at 14301 Lochridge Boulevard, Covington, Georgia, averaging 0.65 pounds of ethylene oxide per hour, which calculates to approximately 5,600 pounds ethylene oxide per year.

**WHEREAS**, on December 18, 2019, EPD issued a Notice of Violation to BD for operating the GDC without an air quality permit as required by Subparagraph 391-3-1-.03(6)(i)(v) of the Rules for Air Quality Control.

**WHEREAS**, on December 20, 2019, BD informed EPD, for the first time, that it had been storing medical devices sterilized with ethylene oxide at a leased warehouse located at 9120 Wheat Street, Covington, Newton County. Also on December 20, 2019, EPD issued a letter notifying BD that the failure to disclose the fugitive emissions information for the Wheat Street warehouse in its December 15, 2019, submittal to EPD was a violation of the Consent Order.

**WHEREAS**, BD agrees to: collect additional air quality sampling data at the GDC and other locations in the Covington, Georgia area; cease sending certain sterilized products to the GDC; permanently remove products that had been temporarily stored at another location in Covington; complete certain engineering analyses related to medical device sterilization and product storage; file a permit application for the GDC; and take other actions as set forth in Attachment 1 to this First Amendment to Consent Order;

**THEREFORE**, upon stipulation and full agreement of the Parties, it is hereby ORDERED that:

1.

The Consent Order executed by this Court on October 28, 2019 remains final and binding on all parties.

2.

In the First Amendment to Consent Order, the Parties agree to and shall implement and complete and take other actions set forth in Attachment 1 to this First Amendment to Consent Order, which is incorporated into and made a part of this First Amendment to Consent Order. Any act required to be done under Attachment 1 shall be enforceable as an order of this Court.

3.

BD agrees to perform all requirements within the time limits and schedules contained in Attachment 1. In the event a Party disputes any aspect of compliance with this First Amendment to Consent Order, the Parties shall first, before bringing any dispute to this Court, attempt to resolve the dispute promptly in good faith between representatives of the Parties with authority to settle the dispute.

4.

This First Amendment to Consent Order is a voluntary settlement of disputed facts and law. The Parties agree that nothing in this First Amendment to Consent Order shall be construed as an admission of fact or a conclusion of law on the part of either Party, and nothing in this First Amendment to Consent Order should be interpreted as acknowledgement of wrongdoing or other improper actions on behalf of either Party. Nothing in this First Amendment to Consent Order shall create any rights, obligations or responsibilities with respect to any third parties.

5.

In the Addendum to the Consent Order entered on October 28, 2019, this Court retains limited jurisdiction over this case until June 30, 2020, for the sole purpose of enforcement of any violations of the Consent Order.

6.

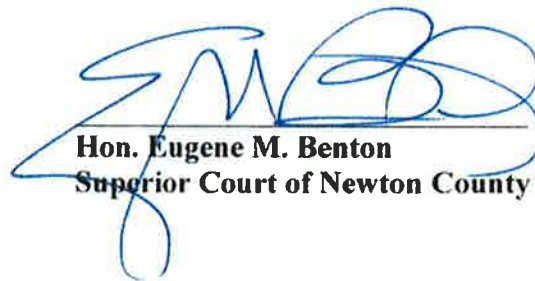
This First Amendment to Consent Order may be modified only upon approval of the Court and the Court retains limited jurisdiction over this case until December 31, 2020, for the sole purpose of enforcement of any violations of the Consent Order or the First Amendment to Consent Order.

7.

Except as specifically set forth in this First Amendment to Consent Order, the Consent Order shall remain valid and effective.

IT IS SO ORDERED.

This 15 day of January, 2020.



**Hon. Eugene M. Benton**  
**Superior Court of Newton County**

**IT IS SO STIPULATED, THROUGH COUNSEL OF RECORD.**

DATED: January 10, 2020

STATE OF GEORGIA

*/s/ Margaret Kemmerly Eckrote*

Margaret Kemmerly Eckrote  
Senior Assistant Attorney General  
State Bar No. 238709

Christopher M. Carr  
Attorney General  
State Bar No. 112505  
Isaac Byrd  
Deputy Attorney General  
State Bar No. 101150  
Robin J. Leigh  
State Bar No. 445845  
Senior Assistant Attorney General

Georgia Department of Law  
40 Capitol Square  
Atlanta, Georgia 30334-1300  
Tel: 404-656-7540  
Attention: peckrote@law.ga.gov

**Counsel for Richard E. Dunn  
Environmental Protection Division  
Georgia Department of Natural Resources**

DATED: January 10, 2020

BALLARD, STEPHENSON & WATERS, LLP

*/s/ W. Michael Waters*

W. Michael Waters  
State Bar No. 740258  
1117 Church Street  
Covington, Georgia 30015  
Phone: (770)-786-8123  
Attention: mwaters@bswattorneys.com

KING & SPALDING LLP

/s/ Douglas A. Henderson

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Douglas A. Henderson

Georgia Bar No. 345537

Nicholas H. Howell

Georgia Bar No. 741064

KING & SPALDING LLP

1180 Peachtree Street, NE, Suite 1700

Atlanta, Georgia 30309

Phone: (404) 572-4600

Attention: dhenderson@kslaw.com

**Counsel for Defendant**

**Becton, Dickinson and Company**

**Attachment 1 to First Amendment to Consent Order**

**Attachment 1 to First Amendment to Consent Order**

1. By agreement of the Parties, BD stopped placing product that has been sterilized using ethylene oxide into its Global Distribution Center (GDC) located at 14301 Lochridge Boulevard, Covington, Georgia on December 23, 2019 at 5 PM. By agreement of the Parties, BD shall not place any products sterilized with ethylene oxide in the GDC until after midnight on January 6, 2020. Going forward, BD shall notify the Georgia Environmental Protection Division (EPD) at least 24 hours prior to placing any product sterilized using ethylene oxide into any warehouse or other storage facility in Georgia other than the GDC, and BD will comply with the requirements detailed in this First Amendment to Consent Order with regard to its storage of sterilized products in the GDC.
  
2. BD shall adhere to the following terms:
  - a. By January 13, 2020, BD shall submit a monitoring plan and schedule to EPD detailing the indoor air monitoring and outdoor fence line monitoring it will conduct at the GDC, using the procedures described in the "Estimation of Fugitive Ethylene Oxide Emissions Report." At a minimum, indoor air and outdoor fence line monitoring shall be conducted weekly. The monitoring plan shall include the date, time, and specific location of the indoor and outdoor fence line monitoring. In the event the date, time, or specific location of the indoor or outdoor fence line monitoring at the GDC are expected to change, BD shall provide 24-hour notice of such change and the basis for such change to EPD, and any such change will be reflected in the air quality sampling results provided to EPD.
  
  - b. By January 13, 2020, BD shall submit a plan to EPD for outdoor ambient air monitoring at the residential areas and school nearest to the GDC. At a minimum, outdoor air monitoring at these locations shall include 24-hour samples collected every 3 days. In accordance with an EPD approved plan, BD shall initiate monitoring by January 17, 2020. EPD will provide comments to BD on the residential and school monitoring plan on or before January 14, 2020, and BD will address those comments and initiate testing on or before January 17, 2020, provided that BD has secured written consent to sample from applicable property owners prior to that date. If BD has not secured written consent from applicable property owners on or before January 17, 2020, BD shall notify EPD and identify the date when sampling is expected to occur. If BD has not secured written consent from applicable property owners on or before January 24, 2020, BD shall initiate testing on those properties where written consent has been secured.
  
  - c. BD shall submit all air quality sampling results to EPD within one business day of BD's receipt of the results. BD shall continue outdoor ambient air monitoring at the residential areas and school nearest to the GDC and indoor air and outdoor fence line air monitoring at the GDC until EPD either issues an Air Quality Permit for the GDC or notifies BD that an Air Quality Permit is not required.



- d. On or before January 13, 2020, BD shall cease accepting Foley catheter procedural trays (Foley Catheter Procedural Trays) at the GDC. Once BD ceases accepting Foley Catheter Procedural Trays at the GDC, BD shall inventory the number of Foley Catheter Procedural Trays stored at the GDC and shall provide certification of that number to EPD on or before January 13, 2020. BD shall be permitted to store individually packaged and sterilized Foley strip catheters that have been subject to at least 24 hours of aeration at the GDC.
- e. By March 2, 2020, BD shall complete the removal of 75% of the Foley Catheter Procedural Trays stored at the GDC and shall certify the removal to EPD. By April 1, 2020, BD shall complete the removal of all Foley Catheter Procedural Trays from the GDC and shall certify the removal to EPD.
- f. By March 31, 2020, BD shall notify EPD of any newly validated sterilization cycle it has submitted to FDA for approval. BD shall notify EPD within one week of receiving FDA approval for a new sterilization cycle at its Madison or Covington facilities. The notification will include the expected reduction in ethylene oxide emissions achieved through the use of the newly approved sterilization cycle at the Covington and Madison sterilization facilities as well as the GDC and a timeline for implementing the new sterilization cycles at the Madison and Covington facilities. Implementation shall occur as expeditiously as practicable.
- g. BD shall immediately undertake an engineering study designed to estimate the impact of increased aeration times and the removal of Foley Catheter Procedural Trays on fugitive emissions of ethylene oxide at the GDC. This engineering study shall include, but not be limited to, estimating the contribution of the Foley Catheter Trays to the ethylene oxide emissions at the GDC (e.g. estimated annual emissions per pallet of Foley Procedural Catheter Trays). By March 1, 2020, BD shall submit the testing results, a description of the methods used, and a discussion of the conclusions and recommendations from the engineering study described in this paragraph to EPD.
- h. BD shall immediately undertake an engineering study designed to more completely identify, define, and quantify fugitive emissions of ethylene oxide released from packaging materials and other materials subjected to a sterilization chamber (with the exception of pallets which will be the subject of another engineering study as detailed in paragraph i). By April 30, 2020, BD shall submit the testing results, a description of the methods used, and a discussion of conclusions of the engineering study described in this paragraph to EPD and BD's plans and a justified timeline for implementing additional steps to reduce fugitive emissions based on findings from the study.
- i. BD shall immediately undertake an engineering study designed to evaluate the reduction in fugitive emissions of ethylene oxide achieved by switching from using a conventional wood pallet to hold medical devices in the sterilization and aeration chambers to an alternative pallet. The study shall quantify the fugitive emissions of ethylene oxide for each alternative pallet considered as well as the wood pallets

currently in use. By May 15, 2020, BD shall submit initial testing results of the engineering study described in this paragraph to EPD. By June 1, 2020, BD will provide EPD a report that describes the testing completed, the methods used, and a discussion of conclusions of the engineering study described in this paragraph and any changes BD will implement as a result of the study and a justified timeline for implementation of such changes.

j. By December 31, 2020, BD shall remove all sterilized products stored in the GDC that were not subject to 24 hours of aeration time in an aeration chamber prior to being stored at the GDC. BD shall accomplish the removal and provide certification to EPD as follows:

(1) BD shall complete the removal of 50% of the products aerated for less than 24 hours from the GDC by April 1, 2020, and shall certify that it has accomplished the removal to EPD on April 1, 2020,

(2) BD shall complete the removal of an additional 25% (for a total of 75%) of the of the products aerated for less than 24 hours from the GDC by October 1, 2020, and shall certify that it has accomplished the removal to EPD on October 1, 2020, and

(3) BD shall complete the removal of an additional 25% (for a total of 100%) of the products aerated for less than 24 hours from the GDC by December 31, 2020, and shall certify that it has accomplished the removal to EPD by December 31, 2020.

3. After January 6, 2020, BD shall not send medical device product to the GDC unless it has been aerated for at least 24 hours.

4. On or before February 14, 2020, BD shall submit the following to EPD:

a. A permit application for the GDC that includes a schedule for designing and installing air pollution control equipment and/or implementing work practices and process optimization projects to reduce ethylene oxide emissions from the GDC.

b. Air toxics modeling using the procedures described in EPD's Toxics Impact Assessment Guideline.

5. On or before January 13, 2020, BD shall provide estimates of the fugitive ethylene oxide emissions occurring at the BD leased warehouse space located at 9120 Wheat Street, Covington, Georgia ("Wheat Street") using a method defined by a third-party engineering firm and approved by EPD, including documentation of the data and engineering calculations supporting those estimates. By agreement of the Parties, BD removed all medical device products sterilized with ethylene oxide from Wheat Street on December 23, 2019. On or before January 13, 2020, BD shall submit the results of the third-party assessment of the Wheat Street location to EPD.

6. To mitigate the impact of these issues, BD shall provide a grant of \$65,000 to the City of Covington, Georgia and a grant of \$65,000 to the City of Madison, Georgia.
7. BD's failure to complete a condition mandated by this First Amendment to Consent Order within the time-period specified may be excused if it is a force majeure event. A force majeure event includes an Act of God; a fire; an explosion; failure to secure timely necessary federal, state, or local approvals or permits, provided the approvals or permits have been timely and diligently sought; or inability to secure required equipment, tools or materials from third parties after using all commercially reasonable efforts to do so. If a force majeure event occurs, BD shall provide EPD with oral notice as soon as it becomes aware of the force majeure event and written notice of the event not less than one business day after it arises. Thereafter, BD shall complete all required sampling, submission or monitoring as promptly as possible after the force majeure event is resolved. BD's failure to provide EPD with the notification required in this paragraph shall constitute a waiver of a claim of force majeure. Any deadlines contained in this First Amendment to Consent Order that are affected by a force majeure event will be extended solely at the discretion of EPD.

