



December 15, 2019

VIA ELECTRONIC TRANSMISSION

Karen Hays - via email
Chief, Air Protection Branch
Georgia Environmental Protection Division
4244 International Parkway, Suite 120
Atlanta, GA 30354

RE: October 28, 2019 Consent Order – Fugitive emissions estimates from offsite warehouse

Dear Ms. Hays,

We are submitting this report in compliance with Paragraph 10 of Attachment A to the October 28, 2019 Consent Order. The report identifies the sample locations, describes the testing results, and contains an initial estimation of fugitive ethylene oxide emissions from BD's Global Distribution Center (GDC) in Covington, Georgia. The estimates provided were calculated in accordance with the plan approved by the EPD on November 19, 2019.

The GDC is a warehousing and distribution operation that receives ethylene oxide-sterilized medical products from BD's nearby sterilization facilities in Covington and Madison, Georgia, as well as from contract EtO sterilization facilities outside of the state of Georgia and ships out these products to customers. At the time of the indoor sampling events, the inventory in the GDC contained a mix of both products which had gone through longer aeration times under the terms of the Consent Order (i.e. 24 hr. aeration) and product in inventory that was sterilized prior to the Consent Order being in effect (i.e. less than 24 hr. aeration).

Results from these initial sets of indoor ambient air sample results, taken below the inlets of exhaust fans, were higher than anticipated. We have initiated an additional evaluation to further understand these results and identify actions to address these emissions.

Actions already in progress include:

- Increasing the frequency of employee exposure monitoring from quarterly to monthly to continue to demonstrate there are no excursions of OSHA exposure limits. We monitor employee exposures from an OSHA perspective on a quarterly basis, and the

results of that testing shows that while EtO is present in the building, workers are not being exposed above OSHA limits. BD is in the process of procuring the additional monitoring badges needed, which have recently been in short supply.

- Initiating a regular frequency of outside samples at the fence line of the GDC to monitor ambient concentrations. Based on the testing data collected to date, we have not seen appreciable levels above average background in the EtO samples taken thus far and will continue to monitor along the fence line.
- Investigating test methods and lab capabilities to perform additional EtO residual testing on packaging materials, kit components and pallets to understand if there are certain portions of the products, packaging or pallets that are contributing to additional fugitive emissions.
- Analyzing the product stored in Section 3 of the warehouse where we observed the highest readings. Because we store acute urology procedural trays in this location, we are initiating a study to determine the contribution of urology trays on overall GDC emissions.
- Investigating the impact on emissions if we move from wooden pallets to stainless steel or plastic pallets in the sterilization process; and investigating availability (quantity and timing) of procuring stainless steel or plastic pallets.
- Investigating the impact on sterilization validations if we were to add additional air-washes in the sterilization chamber before the treated products are moved into the aeration chamber.
- Continuing with additional indoor air sampling at the GDC to determine if the recent readings from those sections of the warehouse are consistent or anomalies, and to further understand the impact on emissions from the extended aeration now in place. We are also taking samples from the Work in Progress (WIP) warehouses in Covington and Madison to gather more data.

We have also devised 30, 60, 90 and 120-day plans for additional actions we will take based on the results of the additional data gathering and laboratory analysis currently underway. These plans include actions such as:

- Performing a comprehensive series of laboratory analysis of residuals from all components of product and storage materials – including outer corrugated cardboard and pallet materials.
- Filing required documentation with FDA to gain approval of an alternative sterilization process, Cycle 15, which we believe could reduce product EtO residuals by 30-50%.
- Identifying possible options for controlling fugitive emissions from the GDC (e.g., installing dry beds or other abatement systems).
- Investigating additional process aeration options at both Covington and Madison.
- Continuing to monitor outdoor air at sample points at the GDC.

We know that more data will be needed to better understand the impacts of product off-gassing. We are now putting real world information to parts of the supply chain not evaluated before and believe that gathering this information from our operations will help provide information that both BD and EPD are seeking with regard to fugitive emissions from commercial sterilization operations. We also note that the US EPA identified the possibility of greater than previously suspected levels of fugitive emissions from sterilized medical devices in the Advanced Notice of Proposed Rulemaking which just appeared in the Federal Register on December 12, 2019.

We are also pleased to report that BD had one of 12 proposals selected by FDA for that agency's Innovation Challenge. Part of our proposal was to improve cycles to use less EtO gas during treatment, which would reduce EtO residuals in products. Pending the results of the product, packaging and storage material analyses referenced above, this work may be even more critical than previously thought.

We would welcome a working session with EPD technical staff in early January to inspect the Global Distribution Center and review these additional assessment efforts in more detail. Please let me know if we can set up a conference call next week to discuss.

Sincerely,



Ellen Kondracki

Vice President, Sustainability
and Environment, Health & Safety

1 Attachment

cc: Peggy Eckrote, State of Georgia, Office of the Attorney General (w/attach.)
Michelle Quinn, BD (w/attach.)
Doug Henderson, King & Spalding (w/attach.)
Les Oakes, King & Spalding (w/attach.)