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December 23, 2019

VIA ELECTRONIC TRANSMISSION

Karen Hays, via email
Chief, Air Protection Branch
Georgia Environmental Protection Division
4244 International Parkway, Suite 120
Atlanta, GA 30345

Re: BD Response to December 18, 2019 EPD Technical Questions Concerning GDC Product Storage

Dear Ms. Hays,

In addition to the information contained in BD's December 20, 2019 initial response to EPD's December 18, 2019 notice letter, BD is providing additional information in response to the technical questions raised by EPD concerning the BD Global Distribution Center (GDC) and other matters related to the storage of sterilized medical devices in Covington.

1. **The outdoor monitoring data mentioned on page 2 of the cover letter to the "Estimation of Fugitive Ethylene Oxide Emissions Report."**

   As described in its December 15, 2019 submission to EPD, BD collected two air samples for ethylene oxide (EtO) at outdoor locations at the GDC. The outdoor samples were collected on two separate dates and included in the report provided to EPD on December 15, 2019. As shown on Figure 1 in Exhibit 1, one of the outdoor sample locations at the GDC was located at the west exterior wall of the GDC, and the other sample location was located at the fence line to the southwest of the GDC. The results below confirm that EtO levels in the ambient air outside of the GDC are in line with background EtO levels found by both Georgia EPD and EPA at air monitoring sites in Georgia and across the country where there are no industrial sources of EtO.

   Following completion of the "Estimation of Fugitive Ethylene Oxide Emissions Report" and BD's evaluation of the results, BD instructed its engineering firm to mobilize for additional outdoor sampling to continue monitoring ethylene oxide concentrations at the outdoor sample locations. This recent voluntary action included securing an adequate supply of summa canisters (which are in short supply nationally) to perform both indoor and outdoor air quality sampling. The first additional samples were collected at the outdoor sample locations on December 20, 2019. Figure 2 in Exhibit 1 contains the laboratory analysis for the sampling. BD will transmit

subsequent air quality sampling results within one business day of BD's receipt of the results.

Sample Location	Sample ID	Sample Date	Results (ug/m3)
West Wall	W1	Nov. 21-22, 2019	0.93
West Wall	W1	Dec. 4-5, 2019	0.30
West Wall	W1	Dec. 20-21, 2019	*Pending*
Average: West Wall*			0.62
Southwest Perimeter	P1	Nov. 21-22, 2019	0.76
Southwest Perimeter	P1	Dec. 4-5, 2019	0.30
Southwest Perimeter	P1	Dec. 20-21, 2019	*Pending*
Average: Southwest*			0.53
** Average = Arithmetic mean. Because EtO risks are measured over a long-time horizon (i.e. consistent exposure over 70 years), it is customary to consider the average of air monitoring samples at a single location. While arithmetic mean is typically used for large data sets and the median or geometric mean is typically used for small data sets, the arithmetic mean is used for simplicity purposes.*			

The samples collected on December 20, 2019 also serve as the initiation of the weekly indoor air monitoring and outdoor fence line monitoring at the GDC.

2. **Updated information on the actions taken or to be taken to address the ethylene oxide emissions at GDC as described in the cover letter to the "Estimation of Fugitive Ethylene Oxide Emissions Report."**

As noted in BD's December 15, 2019 submission to EPD, BD does not conduct medical device sterilization operations at the GDC. As a global distribution center, the GDC receives sterilized medical device products from other locations, primarily from the Covington and Madison BD facilities, and then BD distributes those products to hospitals, medical providers and other health-care providers across the United States and the world. The GDC operates seven days per week with a strong team of experienced and dedicated BD employees, contract security providers and contingent workers.

Short Term (0-60 days) Actions:

After receiving the results of its EtO testing at the GDC, BD took several actions to understand the recent EtO sampling results, from reassessing the sampling results, consulting third-party experts, and reviewing U.S. EPA Subpart O regulation of ethylene oxide. With respect to the EtO product emissions at the GDC, going forward, BD will conduct additional air monitoring as described in the "Estimation of Fugitive Ethylene Oxide Emission Report" and as further described below. BD will voluntarily conduct additional EtO air monitoring both inside and outside the GDC to better understand the impact of the product movement and other remedial actions expected to reduce the fugitive air emissions at the GDC. BD is also in the process of developing an action plan (see page 7, timeline in response to paragraph 9 request) to remove all products from the GDC that were processed prior to the October 28, 2019 Judicial Consent Order and did not use the 24-hour aeration process agreed to by BD and EPD, which should further reduce product emissions at the GDC.

Medium Term (60-120 days) Actions:

BD will conduct an engineering study to more completely define fugitive emissions released from various product packaging materials, pallets used for product storage

and transport. Those engineering analyses and emissions estimation investigations will help inform BD and EPD concerning next steps to further reduce fugitive product emissions at the GDC. Engineering studies will be executed within the current production limits outlined in the Judicial Consent Order, and we expect these studies to be completed with 90 – 120 days.

As part of this effort, BD is working to procure an alternative to wood pallets. Based on preliminary studies, we have identified the substitution of wood pallets as a potentially significant opportunity to reduce EtO consumption and product emission residuals. BD expects to begin receiving and evaluating the new pallets within the next 120 days. The pallet size required for BD sterilization equipment is a non-standard pallet which requires custom manufacturing. Full conversion is expected in less than 180 days.

Along with these steps, BD sterilization assurance teams are working to determine if additional modifications can be made within our FDA-validated and FDA-approved sterilization cycles to improve EtO removal efficiency. Engineering studies will be executed within the current production limits outlined in the Judicial Consent Order, and we expect these studies to be completed within 90 – 120 days.

Longer Term (9-12 months) Actions:

BD has developed a new sterilization cycle that is estimated to reduce fugitive emissions by approximately 30%. The new sterilization cycle has been validated in a portion of the chambers in Covington and Madison with validation in other chambers planned after initial implementation. The new sterilization cycle will be submitted to FDA for approval by February 15, 2020, and BD will request an expedited review by the FDA. BD is committed to conducting these studies within the current production limits outlined in the Judicial Consent Order.

Along with the engineering studies specific to cycle optimization, BD is also evaluating the implementation of other engineering controls, such as additional heated aeration in Covington and Madison and installation of fugitive emissions control equipment at the GDC. Our engineering teams estimate the design, construction, and validation of the additional EtO controls beyond the efforts described above will be completed within 9-12 months and are dependent upon BD's ability to secure the necessary building permits from local officials in Covington and Madison. Additional details will be provided to EPD as these activities progress and as the above changes are implemented.

In conclusion, it is important to note that based on employee monitoring at the GDC, BD's results indicate average EtO levels inside the GDC are approximately 65% below the permissible exposure limits set by the Occupational Safety and Health Administration (OSHA), which is the regulatory authority for EtO levels inside business facilities. In addition, laboratory testing has also confirmed BD products are in compliance with the FDA standards for residual EtO levels that ensure patient and health care worker safety. Nonetheless, we are committed to taking additional steps to reduce fugitive product emissions from the GDC as set forth above.

3. **The amount of product sterilized using ethylene oxide in the GDC as of the date of this letter, broken down as follows: sterilized at BD Covington; sterilized at BD Madison; sterilized at BD facilities located outside of Georgia; sterilized at non-BD facilities located in Georgia; and sterilized at non-BD facilities located outside of Georgia. If the unit of measure is not pounds, include an explanation of the unit of measure.**

With respect to the quantities of medical device products sterilized using EtO in the GDC, BD has developed the following information. The table below lists the EtO sterilized products stored at the GDC in BD's Stock Keeping Units (SKU). They are individual product units that represent the sellable units from BD to Customers/Patients.

EtO Product Sterilized in:	Units	%
BD Covington, GA	13,423,124	72.4
BD Madison, GA	4,267,950	23.0
BD Outside GA	19,840	0.2
Non-BD GA	0	0
Non-BD Outside GA	822,192	4.4
Total EtO Product in GDC	18,533,106	100

To ensure clarity, the above information only represents units stored in the GDC that have been sterilized by EtO. BD also stores product in the GDC that are sold as non-sterile and product sterilized by alternate methods (i.e., certain products manufactured using materials that can withstand non-EtO forms of sterilization like gamma radiation).

4. **A schedule for establishing air monitoring within 30 days at or adjacent to the nearest residential areas and the nearest school to the GDC. Monitoring frequency shall be no less than 24-hour samples to be collected every three days. The schedule shall also provide that the results of monitoring shall be transmitted to EPD within one business day of receipt.**

In response to this request, BD will finalize a written plan and schedule within 30 days to describe the air quality monitoring to be conducted at or adjacent to the nearest residential areas and the nearest school to the GDC in accordance with EPD's requests. As will be described in the plan, BD will perform the following activities on the schedule below:

- December 23-27, 2019 – Identify the nearest residential areas and the nearest schools to the GDC where samples will be collected and compile these areas into a sample location list.
- December 30, 2019 – January 3, 2020 – Finalize access agreement documents to be used with property owners, if necessary, where sample collection is to take place.
- January 2-15, 2020 – Confirm sample location list with EPD and seek access from property owners for sample placement and frequency.
- No later than January 17, 2020 – Initiate sampling.

As requested by EPD, air quality monitoring frequency will be no less than 24-hour samples on an every 3-day frequency. BD will transmit the results of each monitoring event to EPD within one business day of receipt by BD.

As for one key technical limitation, BD is working to secure an adequate supply of summa cannisters needed to perform both this outdoor sampling protocol as well as weekly indoor monitoring at the GDC using the procedures described in the "Estimation of Fugitive Ethylene Oxide Emissions Report." Because of a shortage of summa canisters, BD will make all reasonable efforts to secure the quantities required. If BD is unable to secure adequate supply of summa canisters for any of its planned sampling events, BD will notify EPD of the supply issue within 24 hours and provide a description of the number of canisters in short supply, all efforts taken to secure the necessary canisters, and anticipated timeframe by which cannisters will be secured. In the case of such an event, BD will work with EPD to prioritize the placement of cannisters at sampling locations.

5. **The locations of any other warehouses in Georgia in which BD places product sterilized using ethylene oxide. Include in your response the amount of product sterilized using ethylene oxide. Include in your response the amount of product sterilized and where that product was sterilized using ethylene oxide.**

As noted in its December 20, 2019 Supplemental disclosure to EPD, BD recently leased a 40,000 SF climate-controlled storage space located at 9120 Wheat Street, Covington, GA 30014. This space was used exclusively for overflow storage of products requiring controlled storage temperatures. Since this space was leased on May 1, 2019, BD has stored certain medical device products requiring temperature-controlled storage. No Foley Catheter Procedural Trays were stored at the Wheat Street storage space, and no BD employees work in that location on a continual basis.

As for medical device products sterilized using EtO, the table below summarizes the quantities stored at the Wheat Street storage space since BD leased it on May 1, 2019.

BD Product at Wheat Street	Units	%
Not EtO Sterilized	0	0
BD Covington, GA	91,004	63.4
BD Madison, GA	48,165	33.6
Non-BD Contract Sterilizers Outside of GA	4,320	3.0
Total*	143,489	100
**NOTE this comprises less than 1% of the medical devices at the GDC*		

As of December 23, 2019, in accordance with the State's request on December 20, 2019, all sterilized medical device products in the Wheat Street storage space have been removed. Attached in Exhibit 2 are photographs of the Wheat Street storage space before and after removal of the medical device products.

6. **An explanation of why the post-aeration ethylene oxide emissions at the GDC are not consistent with the information contained in the permit applications for BD Madison and BD Covington. Specifically, the December 15, 2019, report appears to suggest that the amount of ethylene oxide that remains in the product after it leaves the aeration chamber is higher than estimated in the permit applications. Include any past evaluations or monitoring of ethylene oxide emissions that are relevant to your explanation.**

In considering the stored medical device product emissions at the GDC, BD has historically, and consistent with standard industry practice, tested for EtO residuals to determine the criteria for product release and subsequent sale in accordance with FDA guidance and guidance detailed in *ANSI/AAMI/ISO 10993-7:2008/(R) 2012, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residual*s. This information, specific to product as grouped by EtO residual families, was used as the basis to estimate the fugitive emissions from sterilized product for the air permit applications for Covington and Madison. The method of establishing EtO residual families (based on similar materials and product configurations) was and is used to reduce the complexity of EtO residual testing for the more than 10,000 product codes sterilized with EtO at Covington/Madison.

As a result of recent air monitoring results at the GDC, BD recognizes a need to consider other information in addition to ANSI/AAMI/ISO 109993-7:2008 for determining fugitive emissions from palletized sterilized product given the ANSI/AAMI/ISO 109993-7:2008 Standard is specific to EtO residuals in the product (i.e., the medical device). While BD and others are continuing to research this issue, it appears the ANSI/AAMI/ISO 109993-7:2008 Standard does not fully account for EtO residuals in the various packaging materials, or pallets, all of which are also subject to the sterilization process. At this point, based on preliminary analyses and ongoing investigations, we believe that EtO residuals in these materials account for a large portion of the fugitive emissions observed at the GDC.

To further our understanding of various materials and product configurations under various processing conditions, BD is in the process of designing and completing a comprehensive engineering study to determine EtO residuals in all materials subject to the sterilization process. We estimate this study will take 90 to 120 days to complete given a range of technical and product challenges (i.e., BD stores at the GDC over 8,500 different product SKUs that are sterilized in various packaging configurations). With this effort, BD should have additional data to more precisely estimate total fugitive emissions at both the Covington and Madison sterilization plants and the GDC, at which time BD will update permit applications and associated documentation. Currently, there is no recognized U.S. EPA approach to estimate EtO emissions from sterilized medical devices in a distribution center. BD has proposed working with EPD engineering and technical teams to refine the mass-balance equations or other approaches to refine product emissions estimates.

7. **A plan to stop bringing Foley catheter procedural trays into the GDC until such time as an air quality permit is issued to the facility.**

As EPD requested, after December 23, 2019 at 5 PM, BD will not send Foley Catheter Procedural Trays sterilized with EtO at Covington or Madison (or anywhere else) to the GDC, and BD will not resume storage of Foley Catheter Procedural Trays sterilized with EtO at the GDC until an air quality permit for the GDC is issued by

EPD. However, individually packaged Foley catheters which are not sterilized in the procedural kits that contain multiple additional components will continue to be received and distributed from the GDC. These individual Foley catheter products do not contain the accessories in the trays and are not sterilized with as much secondary and tertiary packaging components which BD suspects may retain a higher residual of EtO.

8. **A plan to remove existing inventory of Foley catheter procedural trays out of the GDC.**

BD commits to remove all existing Foley Catheter Procedural Trays from the GDC within 90 days of the date of this letter. BD is further committed to removing 75% of the Foley Catheter Procedural Trays from the GDC within 60 days of the date of this letter.

9. **The amount of product sterilized using ethylene oxide in the GDC, as of the date of this letter, that was not subject to the 24-hour aeration time and a plan to transfer that product out of the GDC.**

With respect to the medical device products sterilized with EtO and stored in the GDC, the table below lists the products stored at the GDC in BD's Stock Keeping Units (SKU). They are individual product units that represent the sellable units from BD to Customers/Patients.

Aeration Period	Units	%
Minimum 24-hr Aeration	10,871,405	58.7
Less than 24-hr Aeration	7,661,701	41.3
Total EtO Sterilized Product in GDC	18,533,106	100

BD commits to reduce the product in the GDC (as of the date of this letter) with aeration times of less than 24 hours as follows:

- 50% within 90 days.
- 75% within 180 days.
- 95% within 270 days.
- 100% within 365 days.

As noted above, all product received by BD at the GDC beginning January 6, 2020 will have completed 24-hour aeration as agreed to by BD and EPD.

10. **Any other information the Company considers relevant to the alleged violation.**

We recognize the important environmental issues addressed in EPD's questions, but we also want to underscore that the sterilized medical devices manufactured at Covington and Madison and stored at the GDC are critical to life-saving health care throughout the United States and the world. BD's medical devices are used in nearly every hospital and healthcare facility in Georgia, including the Piedmont Healthcare System, the Kaiser Permanente System, the Children's Healthcare of Atlanta System, the Atrium Health System, the Advent Health System, the Department of Veterans

Affairs and many others. For example, the following medical devices are routinely sterilized, stored and distributed at or from our Georgia facilities:

- urinary catheters that are used in surgeries over two hours and for critically ill patients in intensive care units,
- PICC lines and implantable Ports that are used to deliver caustic drugs especially chemotherapeutic drugs, total parenteral nutrition and long-term antibiotics for illnesses such as the flu,
- balloon dilation devices used for peripheral arterial disease and end-stage-renal disease, and
- vascular and ureteral stents that are used to open blockages in the peripheral arteries and ureter/urethra.

In particular, the devices sterilized in and/or distributed from our Georgia facilities are used to diagnose and treat patients with cancer (especially breast and liver cancer), end-stage-renal disease, peripheral arterial disease, complex abdominal hernia and reconstruction, and hemostasis to prevent bleeding during advanced surgical procedures. Located in Covington, BD's Urology and Critical Care Business Unit designs and develops products that are used in the majority of patients undergoing surgery and those in intensive care/post-operative care units.

We also want to explain the importance of the sterilization activities at Covington and Madison. EtO sterilization is not only a critical step in the delivery of sterile devices to healthcare providers, it is essential to a functioning and effective healthcare system. Hundreds of thousands of medical, hospital and laboratory processes rely on EtO to sterilize medical devices and equipment to protect patients from the risks of infectious diseases caused by bacteria, viruses and fungi. Since its discovery as an effective sterilant in 1938 for a wide variety of applications, EtO has played an important role in the sterilization of medical devices and pharmaceutical products that protect public health. It is still very effective and the most frequently used sterilization substances available. This is precisely because of its effectiveness, and for life-saving products comprised of more delicate materials that cannot withstand harsher sterilization methods, EtO sterilization is currently the only option to keep patients safe from infection. Like all industrial processes, EtO sterilization can be improved, and BD is already contributing to the U.S. EPA review now underway for EtO.

BD is equally committed to the safe use of EtO sterilization for employees and the community. While all forms of sterilization must be controlled, we have long recognized that the use of EtO creates environmental and safety risks that must be appropriately managed to protect public health and the health of our employees. As noted above, we routinely assess the exposure of our employees to EtO, and air monitoring data from inside and outside our facilities, including the facilities in Georgia in particular, affirm that BD's facilities are safe for employees and the community.

We continue to be committed to operating industry-leading facilities that employ the best available technology, and we have a track record of voluntarily investing in the best available technology to ensure any emissions are within the U.S. EPA's acceptable risk range. The FDA recently invited industry to an innovation challenge to address this issue, and BD was selected by the FDA as one of the companies to participate in developing innovative solutions. BD's proposal for the FDA innovation

challenge program reflects the innovations in cycle optimization combined with the voluntary upgrades we are making in Georgia to address fugitive emissions.

BD operates with the highest degree of ethics, integrity and transparency. We are one of just 17 companies in the world recognized by *Fortune* magazine three or more times in the past five years for our work to improve global health for the betterment of society. BD also has been recognized in the Top 100 Best Corporate Citizens for the past five consecutive years by *Corporate Responsibility Magazine* and was just recently named to *Newsweek* magazine's "America's Most Responsible Companies" list for 2020. BD is also a highly transparent company. BD is one of four companies to receive a perfect score on the 2019 CPA-Zicklin Index of Corporate Political Disclosure and Accountability and is recognized as a trendsetter in political transparency.

While the operational restrictions described in EPD's December 18, 2019 letter as well as those set out in the Judicial Consent Order have reduced our sterilization capacity and required us to devise plans to ship products to and from other BD locations, at this time, we are managing supply for our customers and patients. We appreciate the opportunity to work with EPD, the U.S. EPA, FDA and the Covington and Madison communities in which we operate to ensure that EtO is used in a responsible manner to protect public health, the health of our employees and enable us to serve our global patient population and healthcare providers. Thank you again for your engagement on these challenging issues.

Sincerely

Ellen Kondracki

Vice President, Sustainability
and Environment, Health & Safety

cc: Peggy Eckrote, State of Georgia, Office of the Attorney General
Robin Leigh, State of Georgia, Office of the Attorney General
Michelle Quinn, BD
Douglas Henderson, King & Spalding
Les Oakes, King & Spalding

Exhibit 1: GDC Initial Outdoor Sampling Locations and Laboratory Results

Figure 1: Initial Outdoor Sample Locations

Figure 2: Laboratory Analysis

Sample W1, November 21-22, 2019:

eurofins | Air Toxics

MODIFIED EPA METHOD TO-15 GC/MS SIM
K & S Bard

Client ID:	GDC-W1 20191121		
Lab ID:	1911536-09A	**Date/Time Analyzed:**	11/26/19 01:50 AM
Date/Time Collected:	11/22/19 01:49 PM	**Dilution Factor:**	1.75
Media:	6 Liter Summa Canister (100% SIM Ambier	**Instrument/Filename:**	msd30.i / 30112518sim

Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
2,5-Dimethylfuran	625-86-5	NA	D	0.34	Not Detected
Ethylene Oxide	75-21-8	0.047	D	0.16	0.93

D: Analyte not within the DoD scope of accreditation.

Sample P1, November 21-22, 2019:

eurofins | Air Toxics

MODIFIED EPA METHOD TO-15 GC/MS SIM
K & S Bard

Client ID:	GDC-P1 20191121		
Lab ID:	1911536-10A	**Date/Time Analyzed:**	11/26/19 02:34 AM
Date/Time Collected:	11/22/19 01:41 PM	**Dilution Factor:**	1.71
Media:	6 Liter Summa Canister (100% SIM Ambier	**Instrument/Filename:**	msd30.i / 30112519sim

Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
2,5-Dimethylfuran	625-86-5	NA	D	0.34	Not Detected
Ethylene Oxide	75-21-8	0.046	D	0.15	0.76

D: Analyte not within the DoD scope of accreditation.

Sample W1, December 4-5, 2019

eurofins | Air Toxics

MODIFIED EPA METHOD TO-15 GC/MS SIM
K&S Bard

Client ID:	GDC-W1 20191204		
Lab ID:	1912125-10A	**Date/Time Analyzed:**	12/9/19 11:23 PM
Date/Time Collected:	12/5/19 01:34 PM	**Dilution Factor:**	1.71
Media:	6 Liter Summa Canister (EO)	**Instrument/Filename:**	msd30.i / 30120918sim

Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
2,5-Dimethylfuran	625-86-5	NA	D	0.34	Not Detected
Ethylene Oxide	75-21-8	0.046	D	0.15	0.30

D: Analyte not within the DoD scope of accreditation.

Sample P1, December 4-5, 2019

eurofins | Air Toxics

MODIFIED EPA METHOD TO-15 GC/MS SIM
K&S Bard

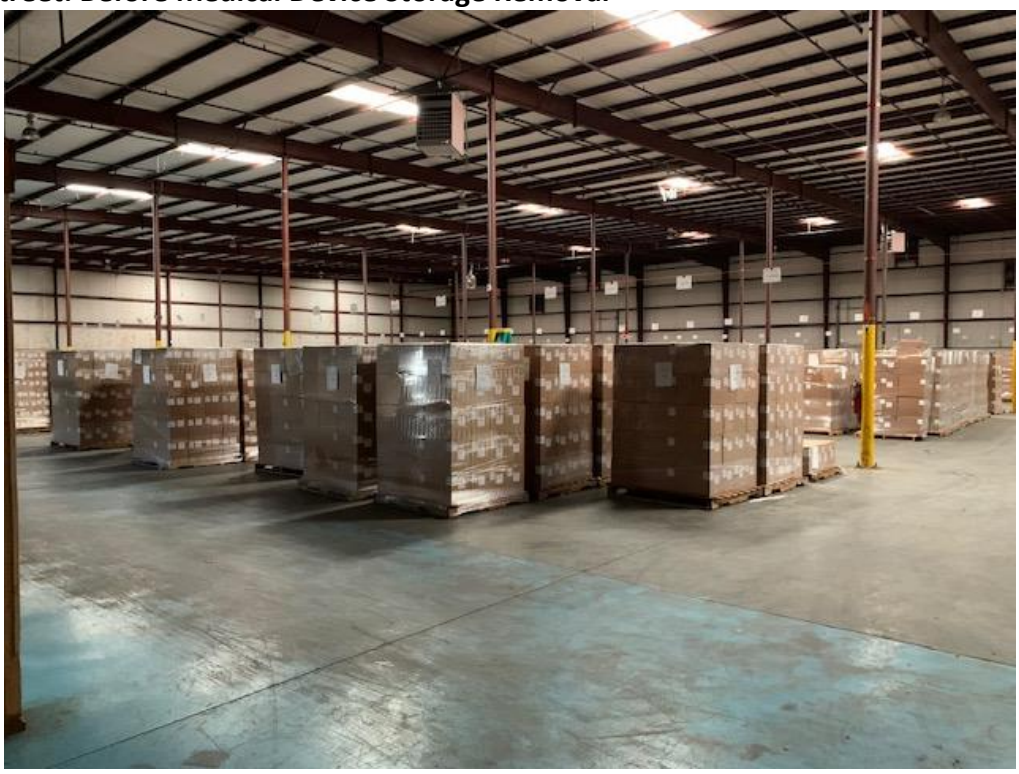
Client ID:	GDC-P1 20191204		
Lab ID:	1912125-09A	**Date/Time Analyzed:**	12/10/19 12:52 AM
Date/Time Collected:	12/5/19 01:24 PM	**Dilution Factor:**	1.68
Media:	6 Liter Summa Canister (100% SIM Ambier	**Instrument/Filename:**	msd30.i / 30120920sim

Compound	CAS#	MDL (ug/m3)	LOD (ug/m3)	Rpt. Limit (ug/m3)	Amount (ug/m3)
2,5-Dimethylfuran	625-86-5	NA	D	0.33	Not Detected
Ethylene Oxide	75-21-8	0.045	D	0.15	0.30

D: Analyte not within the DoD scope of accreditation.

<u>Exhibit 2</u>: Photographs of Wheat Street Storage Space Before/After Medical Device Removal

Wheat Street: Before Medical Device Storage Removal



After Product Removal