DATE: March 2, 2020

TO: Karen Hays, Air Branch Chief, Georgia EPD

FROM: Kimbrell R Darnell, Sr Manager QA Labs

SUBJECT: Consent Order Report, Attachment 1, Article 2, Paragraph (g)

ENGINEERING STUDY

Impact of Increased Aeration Times and the Removal of Foley Catheter Procedural Trays On Fugitive Emissions of Ethylene Oxide at the Global Distribution Center (GDC)

The purpose of this report is to provide information as agreed upon in the First Amendment to the Consent Order, Attachment 1, Article 2, paragraph (g), as well as other pertinent material as follows:

1) An overall summary of the actions taken by BD to date to reduce fugitive ethylene oxide (EO) emissions.
2) An analysis of the effectivity of actions taken to reduce fugitive EO emissions from the GDC based upon a comparative examination of air monitoring data.
3) The details and results of an engineering study carried out to estimate the impact of increased aeration times in the sterilization process and the removal of Foley Catheter Procedural Trays from the GDC, on fugitive emissions of EO.
4) A discussion of the impact of removing the distribution of Foley Catheter Trays from the GDC based upon the engineering study above as well as an estimate of the potential reduction of residual EO on these products with 24 hours post-sterilization aeration.
5) A final summary/discussion of conclusions, next steps, and other recommendations.

1) Summary of Residual EO Reduction Activities to Date

BD has implemented the following modifications to processes and procedures to date:

- Between midnight December 23, 2019, and midnight January 6, 2020, BD ceased placing EO sterilized product into the GDC.
- As of January 6, 2020, the GDC is no longer accepting EO sterilized product with less than 24 hours aeration.
- Prior to January 13, 2020, BD stopped shipment of Foley Catheter Trays to the GDC.
- BD has initiated removal of Foley trays with less than 24 hour aeration from the GDC. To date, approximately 75% of Foley trays have been removed.
- BD has initiated removal of other products with less than 24 hour aeration from the GDC. To date, approximately 44% have been removed.

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The combined effect of these actions has reduced EO fugitive emissions at the GDC by approximately 50% from the initial estimate, the details of which are discussed below.

2) Effectivity of Fugitive EO Emission Reduction Compared with Air Monitoring

BD has contracted with a third party to perform ambient air sampling inside the GDC, at the fence-line of the GDC, and at receptors within the community. The ambient air sampling inside the GDC is intended to monitor fugitive emissions. Although some variation occurs week to week, there is an overall downward trend, supporting our assertions that increased aeration and removal of Foley Trays from the GDC have a favorable impact on fugitive emissions

Ongoing sampling inside the GDC indicates substantial reduction in fugitive emissions. The initial sampling completed on November 21, 2019 indicated an estimate of approximately 6,149 lbs of fugitive EO emissions per year from salable product stored at the GDC (Table 1, Figures 1.1, 1.2). The mean, median, and geometric mean of all sampling results to date are 2,833 lbs, 2,646 lbs, and 2,413 lbs respectively.

Table 1. GDC Fugitive EO Emissions Testing – Indoor

Date	Location	Mass Rate in Pounds per Hour	EO Fugitive Emissions (lbs/yr)
21-Nov	Indoor Fugitive Emissions (Initial Estimate)	0.702	6150
04-Dec	Indoor Fugitive Emissions	0.606	5309
20-Dec	Indoor Fugitive Emissions	0.372	3259
26-Dec	Indoor Fugitive Emissions	0.313	2742
02-Jan	Indoor Fugitive Emissions	0.16	1402
08-Jan	Indoor Fugitive Emissions	0.122	1069
15-Jan	Indoor Fugitive Emissions	0.302	2646
25-Jan	Indoor Fugitive Emissions	0.134	1174
31-Jan	Indoor Fugitive Emissions	0.15	1314
5-Feb	Indoor Fugitive Emissions	0.404	3539
12-Feb	Indoor Fugitive Emissions	0.292	2558
GDC Indoor Sample Average (Mean)		**0.323**	**2833**
GDC Indoor Sample (Median)		**0.302**	**2646**
GDC Indoor Sample (Geometric Mean)		**0.275**	**2413**

Figure 1.1. GDC Fugitive EO Emissions Estimates

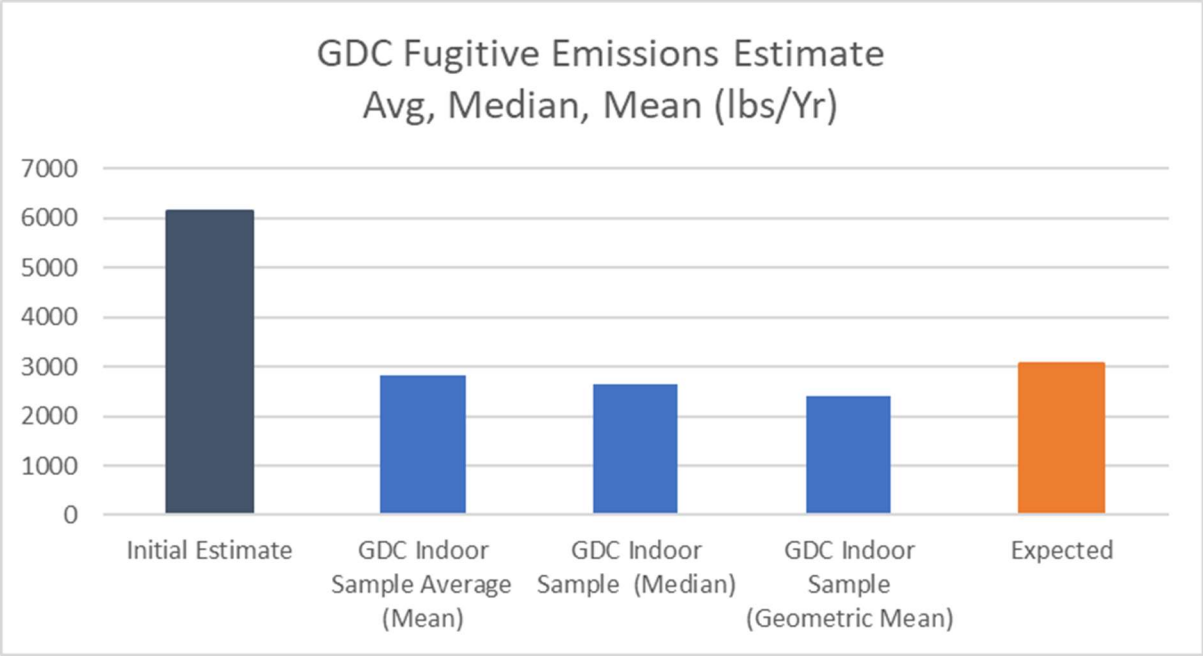
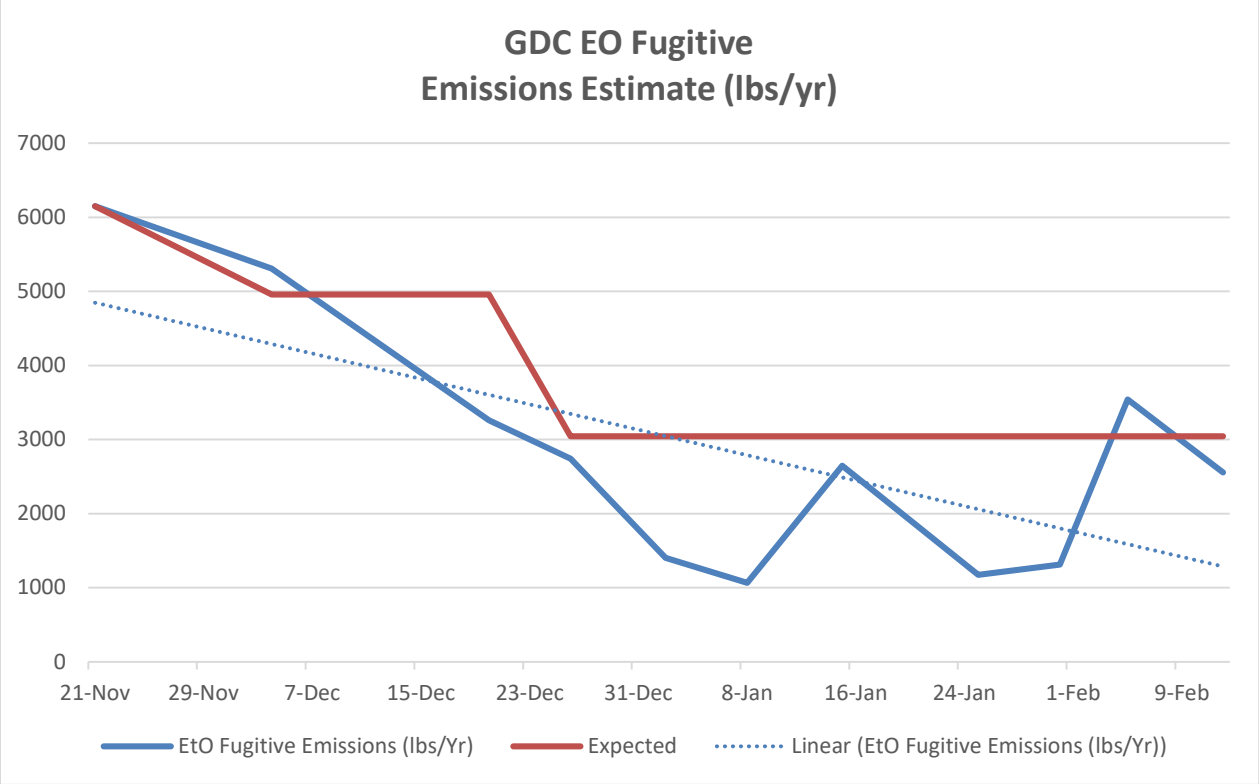


Figure 1.2. GDC Fugitive EO Emissions Estimate vs Expected -Indoor

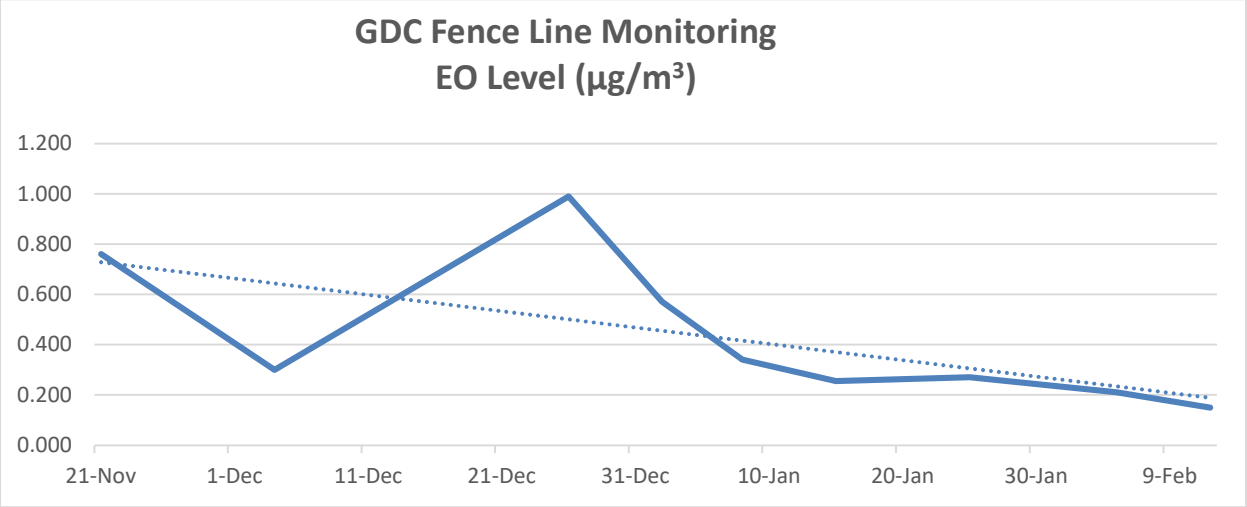


Ongoing ambient air sampling at the fence-line of the GDC shows levels at or near typical urban ambient background concentrations of EO (Table 2, Figure 2.1).

Table 2. GDC Outdoor Ambient Air Samples – Fence Line

Date	Location	EO Level (µg/m³)
21-Nov	GDC Fence Sample	0.760
04-Dec	GDC Fence Sample	0.300
26-Dec	GDC Fence Sample	0.990
02-Jan	GDC Fence Sample	0.570
08-Jan	GDC Fence Sample	0.340
15-Jan	GDC Fence Sample	0.255
25-Jan	GDC Fence Sample	0.270
05-Feb	GDC Fence Sample	0.210
12-Feb	GDC Fence Sample	0.150
GDC Fence Sample Average (Mean)		**0.427**
GDC Fence Sample (Median)		**0.300**
GDC Fence Sample (Geometric Mean)		**0.357**

Figure 2.1 - GDC Fence Line – Ambient Air Samples



Additionally, BD has initiated ambient air monitoring at four receptor sites within the community. Monitoring data at these locations indicate levels at or near typical urban ambient background concentrations of EO (Tables 3.1-3.5).

Table 3.1. Ambient Air Sampling – Alcovy

Date	Location	EO Level (µg/m^3)
17-Jan	Alcovy Area	0.130
20-Jan	Alcovy Area	0.120
23-Jan	Alcovy Area	0.280
26-Jan	Alcovy Area	0.085
29-Jan	Alcovy Area	0.170
01-Feb	Alcovy Area	0.180
04-Feb	Alcovy Area	0.110
07-Feb	Alcovy Area	0.140
10-Feb	Alcovy Area	0.100
Alcovy Area Average (Mean)		**0.146**
Alcovy Area (Median)		**0.130**
Alcovy Area (Geometric Mean)		**0.137**

Table 3.2. Ambient Air Sampling –Nearest School/Hwy 278

Date	Location	EO Level (µg/m^3)
17-Jan	Nearest School/Hwy 278	0.099
20-Jan	Nearest School/Hwy 278	0.071
23-Jan	Nearest School/Hwy 278	0.260
26-Jan	Nearest School/Hwy 278	0.170
29-Jan	Nearest School/Hwy 278	0.160
01-Feb	Nearest School/Hwy 278	0.200
04-Feb	Nearest School/Hwy 278	0.120
07-Feb	Nearest School/Hwy 278	0.160
10-Feb	Nearest School/Hwy 278	0.110
Nearest School/Hwy 278 Average (Mean)		**0.150**
Nearest School/Hwy 278 (Median)		**0.160**
Nearest School/Hwy 278 (Geometric Mean)		**0.140**

Table 3.3. Ambient Air Sampling – Riverbend

Date	Location	EO Level (µg/m³)
17-Jan	Riverbend Area	0.095
20-Jan	Riverbend Area	0.100
23-Jan	Riverbend Area	0.240
26-Jan	Riverbend Area	0.120
29-Jan	Riverbend Area	0.240
01-Feb	Riverbend Area	0.250
04-Feb	Riverbend Area	0.110
07-Feb	Riverbend Area	0.160
10-Feb	Riverbend Area	0.170
Riverbend Area Average (Mean)		**0.165**
Riverbend Area (Median)		**0.160**
Riverbend Area (Geometric Mean)		**0.154**

Table 3.4. Ambient Air Sampling – Settlers Grove

Date	Location	EO Level (µg/m³)
17-Jan	Settlers Grove	0.081
20-Jan	Settlers Grove	0.130
23-Jan	Settlers Grove	0.370
26-Jan	Settlers Grove	0.290
29-Jan	Settlers Grove	0.130
01-Feb	Settlers Grove	1.500
04-Feb	Settlers Grove	0.130
07-Feb	Settlers Grove	0.220
10-Feb	Settlers Grove	0.180
Settlers Grove Average (Mean)		**0.337**
Settlers Grove (Median)		**0.180**
Settlers Grove (Geometric Mean)		**0.218**

Table 3.5. Ambient Air Sampling–Summary

Summary	EO Level (µg/m³)
All Location Average (Mean)	**0.199**
All Location Average (Median)	**0.150**
All Average (Geometric Mean)	**0.160**

3) Engineering Study on Foley Catheter Trays

An engineering study was carried out by BD to estimate the overall contribution of Foley Catheter Trays to fugitive EO emissions as well as the reduction in EO emissions from increasing aeration from 16 hours to 24 hours. The testing was carried out to estimate the total EO residue content per pallet (inclusive of product, package, pallet) prior to the start of aeration, and at the end of 16 hours of aeration. From this data, the amount of residual EO contributed to the GDC can be calculated, and the rate of EO desorption determined during aeration can be used to predict the level of residual EO after an additional 8 hours of aeration (24 hours). The method employed was as follows:

The study consisted of selecting a representative Foley Catheter Tray product load that was sterilized with a routine EO cycle (Cycle 7) for that product. Samples were selected for testing from palletized product prior to the start of aeration and after 16 hours of aeration. Individual cases of product were chosen from two locations on the pallet. One from a case internal to the pallet and one from a case in an external location, i.e. an outside facing layer. Comprehensive EO residue testing was carried out on all parts of the palletized product configuration including the shipping container, the product packaging, all components contained in the product, and finally the shipping pallet the product is stacked on. For comparison purposes, both wood and plastic pallets were included in testing however, data from wood pallets were used for the overall calculation as this is the pallet in current use. All samples were subjected to multiple extraction in purified water to ensure exhaustive extraction of residual EO in accordance with **ANSI/AAMI/ISO 10993-7:2008** ***Biological evaluation of medical devices – Ethylene oxide sterilization residuals*****.** Testing was carried out via gas chromatography direct injection with flame ionization detector in accordance with 10993-7:2008. From these data, an estimate of the total amount of residual EO per pallet was determined prior to aeration and at 16 hours aeration. From this information the data was extrapolated to estimate the reduction of EO from extending aeration to 24 hours.

At the end of the sterilization cycle, and prior to heated aeration (direct from sterilizer), Foley Catheter Tray product was determined to contain 0.1121 lbs of EO per pallet (Pre aeration). At the end of 16 hours of heated aeration the level of residual EO was determined to be 0.0382 lbs of EO per pallet (Post aeration). Based upon these two data points and the log-linear aeration characteristics of EO under steady state conditions of heated aeration, an extrapolation of the residual EO after an additional 8 hours of aeration was determined to be 0.0223 lbs/pallet (Tables 4.1-4.2).

Table 4.1. Comprehensive Analysis to Determine Total Residual EO per Pallet

Product ID	Test Sample ID	Internal Case Pre aeration	External Case Pre aeration	Internal Case Post aeration	External Case Post aeration
	Shipping Pkg	**mg EO**	**mg EO**	**mg EO**	**mg EO**
	[redacted]	0.00	0.00	0.00	0.00
		1.75	2.34	2.28	1.30
		9.83	56.05	2.76	19.66
	Subtotal	**11.58**	**58.39**	**5.04**	**20.96**
	Unit Pkg				
Foley catheter tray Cat # 947418 Lot# NGDX1494 1X Cycle 7	[redacted]	1.80	1.27	1.42	0.53
		0.00	0.09	0.00	0.00
		25.74	17.81	9.88	3.70
		0.92	2.03	1.56	2.68
		0.18	0.16	0.14	0.06
		0.23	0.20	0.28	0.14
	Subtotal per unit	28.87	21.56	13.28	7.11
	Subtotal per case (x10)	**288.70**	**215.60**	**132.80**	**71.10**
	Product				
	[redacted]	0.98	0.86	0.91	0.26
		0.27	0.35	0.45	0.2
		0.28	0.28	0.41	0.18
		5.18	2.07	1.63	0.62
		0.41	0.37	0.17	0.06
		0.89	0.70	0.42	0.25
		5.45	4.25	2.94	2.21
		36.66	27.42	17.86	7.70
		0.08	0.29	0.21	0.22
		0.02	0.03	0.04	0.02
	Subtotal per unit	50.22	36.62	25.04	11.72
	Subtotal per case (x10)	**502.10**	**366.20**	**250.40**	**117.20**
	Total EO Per Case (Pkg + Prod x 10)	**802.48**	**640.19**	**388.24**	**209.26**
	Total EO per # of Cases 13 Internal 53 External	**(802.48 x 13) 10,432.24**	**(640.10 x 53) 33,930.07**	**(388.24 x 13) 5,047.12**	**(209.26 x 53) 11,090.78**
	Total EO/66 Case Pallet	**44,362.31**		**16,137.90**	
	Pallet	**(Wood) 6535.38**	**(Plastic) 137.65**	**(Wood) 1186.00**	**(Plastic) 0**
	Pallet Wrap	**0**	**0**	**0**	**0**
	Residual EO per pallet	**50,897.69 mg 0.1121 lbs**	***44,499.96 mg 0.0980 lbs***	***17,323.90 mg 0.0382 lbs***	***16,137.90 mg 0.0355 lbs***

Table 4.2. Estimation of Residual EO per Pallet at 24 h Aeration by Extrapolation

	0 hrs Aeration	16 hrs Aeration
Residual EO/pallet (wood)	*50,897.69 mg/0.1121 lbs*	*17,323.90 mg/0.0382 lbs*
Calculation of aeration rate. Log(mg) = 10.8376-0.0673582*(Hours)		
Extrapolation of residual EO @ 24 hour = 0.0223 lbs per pallet		

The estimated overall volume of EO sterilized product processed through the GDC is approximately 125,000 pallets/yr. Of this volume, approximately 40% or 50,000 pallets are Foley Catheter Trays.

<u>The impact of 24 hr aeration on fugitive emissions for 125,000 pallets:</u>

0.0382 lbs/pallet (16 hr) – 0.0223 lbs/pallet (24 hr) = **0.0159 lbs/pallet reduction**

0.0159 lbs/pallet*125,000 pallets/yr = **1988 lbs/yr reduction**

<u>The impact of 24 hr aeration on fugitive emissions for 50,000 pallets (Foley Trays):</u>

0.0382 lbs/pallet (16 hr) – 0.0223 lbs/pallet (24 hr) = **0.0159 lbs/pallet reduction**

0.0159 lbs/pallet*50,000 pallets/yr = **795 lbs/yr reduction** (Foley Tray Contribution with 24 hr aeration)

<u>4) Impact of Removing Foley Catheter Tray Product from GDC</u>

Based upon the results of the engineering study, the estimated contribution of Foley Catheter Tray product on fugitive EO emissions at the GDC can be calculated by multiplying the estimated amount of residual EO per pallet by the estimated number of pallets. The residual EO measured per pallet after 16 hours aeration was 0.0382 lbs. Therefore, the net reduction in EO fugitive emissions due to removal of Foley Trays from the GDC:

0.0382 lbs/pallet (Table 4.1) * 50,000 pallets/year = **1,910 lbs/year**

Of the 1910 lbs/yr of emissions related to Foley Trays, the impact of 24 hr aeration and removal from the GDC can be calculated as follows:

0.0159 lbs/pallet*50,000 pallets/yr = **795 lbs/yr reduction** (Foley Tray Contribution with 24 hr aeration)

1910 lbs/yr – 795 lbs/yr = **1115 lbs** (Foley Tray removal from GDC)

5) Conclusion, Recommendations, and Next Steps

This Engineering Study, as confirmed by air monitoring results, estimates that removing Foley Trays and increasing Cycle 7 aeration time to 24 hours reduced emissions at the GDC by approximately 3000 lbs/yr under current operational limitations.

This Engineering Study indicates that significant reductions in fugitive emissions has been achieved by lengthening aerations times and removing Foley Tray product from the GDC. Nevertheless, such reductions may not have the same significance once other process improvements are implemented at the sterilization facility. For example, a combination of cycle optimization aimed at decreasing EO usage and EO residuals, the installation of emissions control systems, and/or modified work practices could reduce fugitive emissions to a level for which increased aeration no longer provides a significant benefit.

As per our commitments, BD intends to continue engineering studies to further quantify EO residuals in products, packaging and pallets. The results of this Engineering Study may be updated as additional information and additional data is obtained. Additionally, BD is committed to install emissions control systems at the GDC and to complete the validation of Cycle 15 (optimized cycle with less EO usage) in sterilization chambers where validation has been completed and to implement Cycle 15 in all sterilization chambers as expeditiously as possible.

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