BD Medical - Pharmaceutical Systems
920 East 19th Street
Columbus, NE 68601
tel: 402.564.3181
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www.bd.com

Certified Mail Receipt: 7018 2290 0001 0769 1142

January 8, 2020

Mr. Kevin Stoner
Air Quality Division, NDEQ
PO Box 98922
Lincoln, NE 68509-8922

RE: NESHAP Summary Report
2nd Half CY 2019
BD Pharmaceutical Systems
IIS #73007

Dear Mr. Stoner:

As required by 40 CFR Part 63, Subpart O, we are submitting a NESHAP summary report for the operation of our ethylene oxide (EO) sterilizer, for the time period July 01, 2019 through December 31, 2019. The report is used to summarize the continuous monitoring system (CMS) performance.

We had no excess emissions during the reporting period. Our sterilizer system is designed so that any emissions normally directed to the catalyst would be diverted to an intermediate balancer tank that stores EO if the catalyst is bypassed for any reason. Therefore, although we have had startup and shutdown events as well as regularly scheduled shutdown time for maintenance and calibration as recorded in our data collection system, these have not resulted in excess emissions and the attached summary sheet indicates zero excess emissions.

The critical operating parameter for the catalytic oxidizing unit (Lesni) is the catalyst bed operating temperature of 150 degrees C, based on the manufacturer's recommended minimum operating temperature. The control system continuously monitors the bed temperatures and shuts down the oxidizer and sterilization processes when the bed temperature falls below 150 degrees C. A strip chart recorder records the average daily oxidation temperature, and these charts are maintained on file. As noted in the enclosed summary report, there were no operating parameter deviations during the reporting period.

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Because the total duration of control system parameter exceedances for the reporting period is less than 1 percent of the total operating time for the reporting period, and CMS downtime for the reporting period is less than 5 percent of the total operating time for the reporting period the full excess emissions and CMS performance report do not need to be submitted as per 63.10(e)(3)(vii). Therefore, only the summary report is being submitted.

If you have any questions, please call me at 402-835-3214.

Thank you.

Jaime Petersen BSN RN COHN
EHS Leader

NESHAP Summary Report

Summary Report - Gaseous and Opacity Excess Emission and Continuous Monitoring System Performance

IIS-73007
Becton Dickinson Pharmaceutical Systems
920 E. 19th St.
Columbus, NE 68601

Reporting period:
From: 07/01/2019 To: 12/31/2019

Operating parameter limit:	150°C minimum catalyst bed temperature
Air pollutant regulated:	Ethylene oxide
Date of last CMS certification or audit	3/25/2019
Process units:	Double-ended Ethylene Oxide Sterilization Chamber
Manufacturer/Model # of Monitored equipment	Getinge: GEE2923118-AR2 EX Sterilizer - project #17020
Total operating time	4054.08 hours

Emission data summary:

Total deviation duration	0.0 hours
Total deviation duration (% of operating time)	0.00%
Duration of each deviation type	
Startup	0 hours
Shutdown	0 hours
Control equipment problem	0.0 hours
Process problem	0 hours
Other	0.0 hours

CMS performance summary

Total CMS downtime	0 hours
Duration of downtime (% of operating time)	0%
Duration of each deviation type:	
Monitoring equipment malfunction	0 hours
Other equipment malfunction	0 hours
QA control calibration	0 hours
Other	0 hours

Changes to CMS, processes or controls since last report	None
	Stack test conducted on 07/12/2019

Signed: William P. Campbell, Dir. of Plant Operations Campbell

Date: Jan 8, 2020