## September 15, 2020

Mr. Sean Taylor Program Manager Stationary Source Compliance Program, Air Protection Branch Georgia Environmental Protection Division 4244 International Parkway, Suite 120 Atlanta, Georgia 30354

## SENT BY EMAIL AND FEDEX

Re: KPR U.S., LLC ("KPR") Replenishment Center, Atlanta, Georgia – September 4, 2020 Notice of Violation Letter

Dear Mr. Taylor:

On behalf of KPR, this responds to your letter of September 4, 2020 (the "NOV") concerning the above-referenced facility ("Facility"). KPR respectfully requests a 30-day extension to respond to the NOV. The additional time will allow for collaboration between KPR and the Georgia Environmental Protection Division ("EPD") and provide KPR with additional time to provide information responsive to the potential issues raised in the NOV.

As noted in the NOV, KPR voluntarily contacted EPD on June 26, 2020 to apprise EPD of preliminary and limited EtO sampling of vent stack emissions at the Facility. Although there was and has been no evidence of any EtO related compliance issue at the Facility based on its robust and OSHA-compliant employee safety EtO monitoring program, KPR undertook this limited testing in light of broader recent EtO regulatory developments not related to KPR facilities to assess whether the Facility, which *does not* sterilize medical products but accepts sterilized medical products (in addition to non-sterilized medical products) in the chain of distribution, may have measurable EtO emission levels solely through product "off-gassing." As noted during the June 26<sup>th</sup> call, the draft sampling did not definitively establish the need for an air permit at the Facility or that a violation has occurred or is occurring. Rather, the test provided a snapshot of emissions at the time of the test, but did not assess whether the preliminary measurements are representative of typical off-gassed emissions at the Facility so as to justify extrapolating the results on an annual basis.

As EPD likely knows, there are no "off-the-shelf" procedures for evaluating product off-gassing and developing reliable emission estimates. KPR proposes to work with EPD to develop both a background testing protocol and a new testing methodology for evaluating EtO emissions from sterilized medical products on a "pallet-by-pallet" basis.

Given the need to develop new processes to evaluate the issues raised in the NOV, and considering the global pandemic that is currently creating an unprecedented need for some of the medical products stored at the Facility, KPR believes that the additional time requested in this letter is critical to ensuring that the issues identified in the NOV are addressed in an appropriate and timely manner without unreasonably impacting patient care. We appreciate your consideration of this request and look forward to working with EPD to determine how KPR can best collaborate with EPD on this matter going forward.

Very truly yours,

Jeremy Currithers

**Director of Operations** 

cc:

Kathryn.Holen@cardinalhealth.com