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June 9, 2021

Mr. James Jones, Air Permit Engineer
Pima County Department of Environmental Quality
33 North Stone Avenue, Suite 700
Tucson, Arizona 85701

Subject: **BD Class II Permit Application – Response to PDEQ Comments received on June 4, 2021**

Dear Mr. Jones:

Becton, Dickinson and Company (BD) would like to thank Pima County Department of Environmental Quality (PDEQ) for their review of the Class II permit application and follow-up discussions on the proposed project. BD has reviewed the comments received from PDEQ via email on June 4, 2021, and submits the following responses.

PDEQ Comment: *How do you propose to monitor the dry bed systems for their proper functioning and efficiency during those periods between tests of the bed media to assure the beds are not bridging or bypassing due to settling etc.*

BD Response*:* The dry bed systems will be operated and maintained in accordance with the manufacturer's recommendations. BD will perform a test and balance of the systems as part of commissioning activities. BD will establish daily verification of air flow and pressure differential across the dry bed systems. BD will also develop a robust PM program to verify the proper operation and integrity of the systems, including but not limited to visual inspection of the media, verification of pressure differential and flow rates, and maintenance of the fan systems and system controls.

PDEQ Comment: *Are there instances wherein the facility may have to back vent without controls in case of emergencies, or is the system designed to rout emergency flow to one of the control systems, in the event an emergency relief valve expels large concentrations of ETO from a process area.*

BD Response: The sterilization chambers will not be equipped with back vents. The automated material handling systems negate the need for operators to enter the chamber during loading and unloading of the chamber. At the conclusion of the sterilization cycle the chamber gas detection systems will verify it is safe to transfer the product from the sterilization chamber to the aeration cells. Fugitive emissions from the transfer of product will be captured and controlled by the drybed system for the chamber rooms.

The site will employ several levels of controls to minimize and mitigate the potential uncontrolled release of ETO from the process equipment.

The process equipment is designed to monitor and control critical process parameters, including but not limited to; temperature, pressure, injection rate, vacuum rate, ETO concentration, and various phase specific parameters and setpoints. The sterilization cycle is carried out at pressures below atmospheric reducing the possibility of a large leak during the sterilization cycle. The vaporizer and process piping will be purged with nitrogen after the gas injection phase reducing the risk of ETO release for subsequent phases of the cycle. Additionally, there are gas

detection systems installed in the processing areas which are interlocked with the process equipment. Any deviation from normal process parameters, loss of utilities, or activation of the gas detection system alarms, will cause the process to stop (in safe mode) until the issue is corrected and it is safe to resume operations.

In the case of accidental release of ETO into the processing areas the drybed systems are designed to capture and control the ETO within this space. In the case where the design limits of the drybed systems is exceeded the emergency exhaust would be activated and the space would be vented to atmosphere. In this case the quantity of the release would be reported to authorities as per State and federal regulatory requirements.

A robust preventive maintenance program will be developed in alignment with manufacturer's recommendations as well as Recommended and Generally Accepted Good Engineering Practice (RAGAGEP). This includes, but is not limited to, leak check of the drum manifold and associated equipment, leak check of the sterilizer prior to use of ETO, routine leak test of the entire sterilization process equipment, calibration of sensors, gas detectors, and critical process control equipment, safety interlock verification, and annual requalification of the sterilization process and associated utilities.

BD will implement a strict ETO drum inspection program which will ensure no leaking drums are received on site or used in the process. BD will also implement a robust Leak Detection and Repair (LDAR) program in accordance with EPA guidance, inclusive of all ETO processing equipment, including safety (emergency) relief valves.

BD will establish and train an on-site HAZMAT Team to enable timely response to emergencies and will develop a comprehensive emergency response plan and coordinate with local emergency response agencies.

PDEQ Comment: *Do we need to consider any of the materials exposed during processing with ETO as hazardous waste either before or after exposure or ETO usage. Disposable filters, or elements, et. al.*

BD Response: The proposed ethylene oxide sterilization facility is not expected to generate hazardous waste from the sterilization process. Any waste generated (i.e. from laboratory or maintenance activities) will be profiled and disposed in accordance with the applicable State and federal regulations.

PDEQ Comment: Determination on what constitutes startup of the operations for setting forth the timeline to the first performance tests.

BD Response: As discussed on conference calls with PDEQ on June 4, 2021, each sterilization system will undergo a rigorous validation to ensure that the final sterilized product meets U.S. Food and Drug Administration (FDA) requirements. The validation process for each sterilization line will include the following protocols:

- Installation Qualification (IQ): This protocol is to confirm all process and support equipment is installed as per design intent. No ethylene oxide will be used during this protocol.

- Operational Qualification (OQ): This protocol is to confirm the equipment operates as intended. This includes running the equipment, testing alarm limits, interlocks, etc. At the conclusion of the OQ the testing will include a dry run (no product) with ETO. Exhaust from the sterilization and aeration (degassing) chambers will be routed to the Lesni catalytic oxidation systems to control emissions of ethylene oxide. The dry bed systems will also be operational at this time.

- Performance Qualification (PQ): This protocol is to confirm medical products can be sterilized as intended. ETO will be used to sterilize dunnage (representative of product to be sterilized) in accordance with FDA requirements. The PQ typically involves 4-6 runs or cycles as per industry guidance.

After the completion of the validation steps, BD will submit documentation for approval of the sterilization equipment and process to the FDA. BD is not allowed to sterilize "sellable" product until an approval from the FDA is received. BD therefore considers the receipt of approval from FDA as initial startup of its sterilization process. As discussed with PDEQ, BD is proposing to complete the initial performance testing of the two Lesni systems within

180 days of the completion of the validation (following completion of the Performance Qualification) for each sterilization line.

If you have questions regarding the information presented in this document, please feel free to contact me at your convenience.

Yours Sincerely,

Travis Anderton

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