

February 5, 2020

Attn: Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Phone: 301-415-7526

Subject: Reply to a Notice of Violation / Docket No. 030-38147 / License No. 10-23980-01E

To Whom It Concerns,

This letter provides the written response to the Notice of Violation dated January 10, 2020 and received January 13, 2020.

For violation A): (1) The reason, or root cause, of the violation was determined to be a lack of a procedure which documents the requirements as well as a mechanism to ensure the summary report is submitted in a timely manner. (2) The corrective steps that have been taken were: submission of amended summary reports for calendar years 2015 – 2018 to the NRC in December 2019 and submission of the summary report for calendar year 2019 on January 6, 2020. (3) The corrective steps that will be taken are as follows: the requirements for the content of the summary reports will be documented in an approved internal procedure, to also include provision for a mechanism—i.e. an automatic reminder to prompt the Avent, Inc. RSO to submit the report prior to the due date. (4) The anticipated date of completion of corrective action (3) is February 28, 2020.

For violation B): (1) The reason, or root cause, of the violation was determined to be inadequate documentation of license requirements. (2) The corrective steps that have been taken are summarized in the preceding paragraph for violation A). (3) The corrective steps that will be taken are summarized in the preceding paragraph for violation A). (4) The anticipated date of completion of corrective action (3) is February 28, 2020.

If you have any questions, please contact me via the information provided under my name.

Sincerely,



Sarah Wolf
Analytical & Microbiology Laboratory Senior Manager
Avanos Medical / Avent, Inc.



5405 Windward Parkway
Alpharetta, GA 30004

T 1-844-425-9273

avanos.com

6620 South Memorial Place, Suite 100
Tucson, AZ 85756
Sarah.Wolf@avanos.com
520-664-2754

Cc: Regional Administrator, Region IV
U.S. Nuclear Regulatory Commission
1600 E. Lamar Blvd.
Arlington, TX 76011