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October 1,2021

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555,

REFERENCE: Reply to a Notice of Violation, Docket No. 03009293, License No. 06-08349-04

One violation was cited based on 10 CFR 35.63(c) where the dose calibrator failed the quarterly linearity at one dosage level, we continued to use the dose calibrator for determination of the patient dosage. The following is our reply:

1. Reason for the Violation: Initially, when the first linearity test failed, the standard procedure is to repeat the measurement to confirm the results. When it was confirmed on the second test, the dosage level where the error occurred was essentially the same for both. This level was not typically a value that is prescribed to our patients. Also at that time, replacement of the dose calibrated was requested and approved, so we expected a fast replacement. Unfortunately, the replacement time was longer than we expected.

2. Corrective Steps Taken: The faulty dose calibrator was replaced and put into service October 22, 2020.

3. Correction Steps Taken for Future: The following procedure was instituted October 1, 2021:
   In the event of a dose calibrator malfunction, the unit dosage assigned by the radiopharmacy will be corrected for decay to the time of the patient administration.
   For kits prepared in the hot lab, the radiopharmacy assigned isotope vial dosage will be corrected for decay, and dosage concentration in mCi/ml will be determined. The volume to be administered to the patient will then be determined by dividing the intended patient dosage in mCi by the vial mCi/ml.

4. Full Compliance was achieved October 22, 2020. Future contingency steps instituted October 1, 2021.

Please let us know if additional information is needed. Thank you for your attention to this matter.

Sincerely,

John Capobianco
Vice President of Operations

CC: Tara L. Weidner, Acting Chief
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