MEDICAL EVENT 15-DAY WRITTEN REPORT TO NRC REGION III

May 7, 2021

U.S. Nuclear Regulatory Commission - Region III
2443 Warrenville Road
Lisle, IL 60532

ATTENTION: Luis Nieves Folch (Luis.NievesFolch@nrc.gov)

SUBJECT: Medical Event of 4/23/2021; 15-Day Report to NRC Region III

License No.: 24-00196-07
Licensee: Saint Louis University
Location of Event: SSM Health Saint Louis University Hospital

Medical Event: At approximately 12:20 p.m. on Friday, April 23, 2021, Y-90 SIR-Sphere was being administered to a patient. The prescribed dose was 43.2 mCi, the measured dose to be administered was 46.7 mCi, but due to a clog in the catheter, only a calculated 4.53 mCi dose was administered to the patient. Because this exceeds +/- 20% of the intended dose, we determined a medical event had occurred. There was no harm to the patient, and a follow-up dose for this patient has been scheduled.

Preliminary Determination of Cause: The cause of the medical event was believed to be clogging of the catheter, but the exact reason for the resistance was undetermined. When the resistance was encountered, the procedure was stopped by the administering Authorized User physician, with the intention of terminating the procedure, resulting in an administered dose variance greater than +/- 20% of the prescribed dose, and thus determined to be a medical event.

Additional Details:

- The Nuclear Medicine Technologist drew the dose per standard operating procedure. The procedure checklist was read and the dose administration set up was normal. All steps to prevent clumping of microspheres were followed.
- During the administration, the dose was agitated and attempted to be delivered. There was resistance on the plunger during the administration. The physician stated that the catheter was clogged. The procedure was stopped, with the intention to terminate the procedure, and to administer a second dose at a later time.
- The physician disconnected the A-line from the patient catheter. This caused the backpressure to expel the beads onto the administration table and the floor covering. The disposable covering of these surfaces were collected and disposed of in radioactive waste. The Interventional Radiology Suite was surveyed and released, with all wipe tests and G-M survey meter readings at background.
- The microcatheter was placed into radioactive waste storage where it remains for radioactive decay.

- The 2.4Fr Microcatheter used in the procedure is manufactured by Accurate Medical Therapeutics Ltd. It meets the Sirtex specifications for administration of SIR-Spheres. The packaging materials have been saved, preserving the reference number, lot number and expiration date of the 2.4Fr Microcatheter that was used for this SIR-Spheres administration, in case determined needed for further investigation. The Microcatheter was well within the designated use period, with an expiration date of 2022-08-06.
- The Authorized User physician involved with this administration promptly notified both the referring physician and the patient the day of the event, April 23, 2021, explaining in detail what happened, immediately after the administration.
- SIR-Spheres Y-90 resin microspheres are manufactured by Sirtex. The local Sirtex Sales Representative routinely attends and observes SIR-Spheres administrations, including at SSM Health Saint Louis University Hospital. He was present during the administration on April 23, 2021. The RSO interviewed the sales representative by telephone on May 7, 2021. The Sirtex Sales Representative stated that during this administration, there was nothing unusual. Everything went as normal. He reported that the Nuclear Medicine staff went through their step-by-step written procedures during the administration as they normally do. The agitation of the SIR-Spheres Y-90 resin microspheres was done as normal. He also stated that the Microcatheter used meets Sirtex specifications. He observed the entire administration, including the Authorized User physician's decision to terminate the procedure after encountering resistance to the plunger during the administration, and thought it was an appropriate decision.
- Neither the Authorized User physician, the Nuclear Medicine Technologist, nor the Sirtex Sales Representative were able to determine a specific cause of the resistance to the plunger.

Follow-up Reporting:

- **24-Hour Telephone Report:** The event was reported to the Radiation Safety Officer (RSO). While awaiting determination of the estimated dose (if any) that may have been administered to the patient, the RSO contacted Region III Inspector, Dennis O'Dowd, who had recently inspected this licensee concluding on April 7, 2021. The RSO was advised that if zero dose entered the patient, it would not be a medical event. However, because it was subsequently determined by the Nuclear Medicine staff that 4.53 mCi was administered to the patient, the RSO reported the Medical Event to the NRC Operations Center at approximately 6:32 PM CDT (Official Notification Time: 19:33 EDT) on Friday, April 23, 2021. The telephone report was immediately followed up with an email report sent to the NRC Operations Center personnel who took the phone call.

- **24-Hour Reporting to Patient and Referring Physician:** The Authorized User physician involved in the administration notified both the referring physician and the patient, with detailed explanation of what happened, immediately following termination of the procedure.

- **15-Day Written Report to NRC Region III:** This report is being emailed on May 7, 2021 to NRC Region III Inspector, Luis Nieves Folch.

Please contact me if you need additional information.

Sincerely,

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