MEDICAL EVENT 15-DAY WRITTEN REPORT TO NRC - NMSS

July 14, 2023

ATTN: Document Control Desk
Director
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: 15-Day Written Report of Medical Event of 6/29/2023; per 10CFR35.3045(d)

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(i) Licensee name: Saint Louis University (NRC License No.: 24-00196-07)
(Location of event: SSM Health Saint Louis University Hospital)

(ii) Name of the prescribing physician: Kirubahara Vaheesan, M.D.

(iii) Brief description of event: On June 29, 2023, at 12:01 pm, a Y-90 TheraSphere procedure was performed lasting until 1:14 PM. The prescribed dose was for 14.58 mCi to the left lobe of the liver. The Authorized User (AU), who is both the prescribing physician and the referring physician, stated that everything seemed to go normally other than he remembered afterwards a little more resistance than usual while injecting the dose. The patient was sent for imaging, per normal procedure, and it was discovered shortly after 3:00 PM that the imaging indicated that none of the Y-90 TheraSphere dose was in the patient. This was investigated, the dose vial and the catheter tubing from the administration were each measured separately in the dose calibrator. About 0.5 mCi was in the vial, with the remainder of the dose, about 14 mCi, in the microcatheter tubing. It was concluded that the particles got clogged within the catheter, preventing delivery to the patient. The AU stated that the catheter used was a Trinav 130 cm length catheter, which is a special catheter with an anti-reflux basket to prevent reflux and specially designed for Y-90 delivery. Because the dose delivered was clearly greater than 20% underdosed, it was reported by telephone to the NRC Operations Center by telephone on June 30, 2023.

(iv) Why the event occurred: During review of the administration with the AU, the AU reported that he had determined the use of extension tubing was needed for this particular patient administration to extend the length of the 130 cm microcatheter because it was too short to proceed with proper set-up. It was a medical decision on the AU's part to use a 20 cm extension catheter to avoid delays in this liver cancer therapy treatment, given the patient's condition. Under these circumstances, the use of the extension tubing allowed the tubing to be hung vertically from the extension arm of the TheraSphere administration kit in accordance with procedures. In follow-up discussion with the TheraSphere manufacturer, Boston Scientific, the use of the extension tubing between the TheraSphere device and the microcatheter was determined to be the root cause of the medical event. Per the manufacturer, the larger internal diameter of the extension tubing will reduce the saline velocity and the microspheres will fall out of suspension, leading to retention of the microspheres in the extension tubing.

(v) The effect, if any, on the individual(s) who received the administration: There was no effect on the patient, other than being prepped for the procedure and having to undergo a repeat procedure two weeks later to deliver the prescribed dose. The patient underwent the repeat procedure on July 13, 2023 and the prescribed dose of 14.58 mCi was delivered within 9.2% (delivered activity to the liver was calculated to be 13.24 mCi). While post-administration imaging of the patient following the initial TheraSphere administration on June 29, 2023 yielded no visible images indicating delivery of any of the Y-90 TheraSphere dose into the patient, a subsequent

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review of the written directives from both administrations allows comparison of post procedure patient survey results and calculation of possible administered activity during the June 29, 2023 TheraSphere attempted administration. Comparing the ion chamber survey results of 2.8 mR/hr in contact with the patient following 13.24 mCi delivered to the liver on July 13, 2023 with 0.21 mR/hr measured in contact with the patient following the administration on June 29, 2023, a calculated 0.993 mCi may have been administered to the patient on June 29, 2023. This had no bearing on the AU's medical decision to repeat the prescribed dose of 14.48 mCi on July 13, 2023, or the ultimate outcome of treatment.

(vi) What actions, if any, have been taken or are planned to prevent recurrence: Because of the manufacturer's assessment that the use of extension tubing is the root cause, extension tubing will not be used on any future cases. Plans are to stock 150 cm anti-reflux microcatheters to assure adequate length for patients presenting with need for this type of catheter. Manufacturer's instructions will be rereviewed by all AUs authorized for Y-90 TheraSphere therapy treatments. This case, including root cause and actions to prevent recurrence, will be reviewed by the AU with the other IR AUs and residents during the monthly IR Mortality and Morbidity meeting, held the first Wednesday of the month. As an additional best practice, we are engaging the TheraSphere manufacturer to provide onsite refresher training for Nuclear Medicine Technologists and AUs.

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not: The AU provided notification to the RSO via email on July 5, 2023 at 2:20 PM that the patient was notified of the underdose on June 30, 2023 at 11:00 AM. It should be noted that the AU is also the referring physician.

Please contact me if you need additional information.

Sincerely,

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Executive Director, Environmental Health and Safety

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