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DANIELLE SHEEN, EXECUTIVE DIRECTOR

November 9, 2018

Robert Gattone
Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region III
Division of Nuclear Materials Safety
2443 Warrenville Road, Suite 210
Lisle, IL 60532

Subject: **Written Notification of Apparent Medical Event (October 25, 2018)**
University of Michigan / Michigan Medicine
Materials License No. 21-00215-04 / Docket No. 030-01988

Dear Mr. Gattone:

In accordance with 10 CFR 35.3045(d), the University of Michigan is submitting a written report describing an apparent medical event that occurred on October 25, 2018, at the University of Michigan. This report summarizes the events prompting notification, assessed causes, and proposed corrective actions.

1. Licensee: The Regents of the University of Michigan
Environment, Health & Safety (EHS) / Radiation Safety Service
1239 Kipke Drive / CSSB
Ann Arbor, Michigan 48109-1010

2. Prescribing physician: Morand Piert, M.D. / Radiology - Nuclear Medicine
Authorized User physician: Ka Kit Wong, M.D. / Radiology - Nuclear Medicine

3. Description of the event:

A patient was prescribed to receive a unit dose of 200 mCi of Lu-177 DOTA^{0}-Tyr^{3}-Octreotate ("Lutathera") on October 25, 2018. Due to issues originating with the infusion setup, the patient received approximately 134.9 mCi. The administered dose deviated from the prescribed dose by >20%, prompting a medical event evaluation. Upon confirmation of the organ doses resulting from the administered dosage, the licensee determined that the event was reportable. The event was reported to the NRC Operations Center on October 26, 2018, by Mark Driscoll, Radiation Safety Officer and Director, Radiation Safety Service, EHS, University of Michigan.

4. Why the event occurred:

The infusion method used on the day of the apparent medical event – the third method employed by the licensee since beginning Lu-177 infusions in June 2018 – had demonstrated the potential for small bubbles to develop in the infusion line, causing the pump to alarm. The nuclear

medicine technologist most experienced with Lu-177 infusions (NMT1) was aware of this issue and knew how to relieve it.

On the day of the apparent medical event, NMT1 was called away from the Lu-177 infusion to administer a therapy elsewhere in the clinic; she left instructions with a second technologist (NMT2) to pause the infusion and contact her, should the pump alarm. Contrary to these instructions, NMT2 attempted to restart the pump after it alarmed, which formed a larger bubble in the line. NMT2 then asked an attending infusion nurse for assistance in purging the line. The nurse did not realize that the saline line was closed, and she was not aware that fully-concentrated Lu-177 was still in the line; she had not been trained to perform this operation (i.e., to purge the line containing Lu-177), which had previously been performed by NMT1. The nurse drained the line empty, into an emesis basin, believing it was saline. She then observed the saline line was closed and realized she had drained Lu-177. NMT1 returned to the infusion, evaluated the events, and determined that approximately 68.3 mCi of the dispensed dosage (203.2 mCi) was not delivered to the patient.

5. Effect, if any, on the individual receiving the administration:

There is no anticipated effect on the patient. A make-up Lutathera dose was administered on the following day, to complete the patient's prescribed therapy.

6. Actions taken or planned to prevent recurrence:

The licensee's short-term and planned corrective actions include:

- The patient received a supplemental Lutathera dose of 66.8 mCi on October 26, 2018, to make up for the apparent under-dose on October 25, 2018. This brought the total dose administered (over two days) to 201.7 mCi.
- All nurses attending to Lu-177 therapies are being formally retrained about the infusion process, their responsibilities (compared to those of the NMT), and general radiation safety.
- Emergency situations notwithstanding, only trained NMTs will "handle" Lu-177, purge or handle lines during the Lu-177 infusion, or otherwise manipulate components involved in the Lu-177 infusion, until the Lu-177 infusion is complete.
- The preferred infusion method has been modified to minimize recurrence of the issue that occurred on October 25, 2018.
- The attending NMT will be responsible only for Lu-177 on days when Lu-177 is administered, until all Lu-177 infusions are complete for the day. The NMT will also be available to oversee the release of Lu-177 patients from the restricted area.
- Additional NMTs will be trained to oversee Lu-177 therapies; NMT1 (identified above) will provide this training and supervise the involvement of other NMTs in Lu-177 therapies, until their experience is deemed adequate to be unsupervised.
- NMTs, nurses, and other staff entering the restricted area where Lu-177 infusions are conducted should wear two pairs of booties, discarding the outer pair before stepping out of the restricted area.

7. Certification that the licensee notified the individual:

The prescribing physician discussed the event with the patient on October 25, 2018. The patient returned to the clinic the following day, to receive a make-up dose and complete the therapy, under supervision of the Authorized User physician.

Please contact me [(734) 764-6200 / drisc@umich.edu] should you have any questions or comments regarding this notification.

Sincerely,

Mark L. Driscoll

Mark L. Driscoll
Director / Radiation Safety Officer
Radiation Safety Service / EHS

cc: Danielle Sheen, CIH, Executive Director, EHS
Ruthann Nichols, Ph.D., Chair, Radiation Policy Committee
Broad Scope Materials License No. 21-00215-04 Files