St Luke's

September 3, 2019

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US Nuclear Regulatory Commission Region IV
1600 East Lamar Boulevard
Arlington, Texas 76011-4511

RE: Medical Event Written Report, License 11-27312-01

To whom it may concern,

In accordance with 10 CFR 35.3045, this written report is provided to the NRC Region IV office following the discovery of records that indicate a possible medical event. The event was discovered on August 29th during a routine review of written directive records. The NRC Operations Center was notified on August 30th, as required by 10 CFR 35.3045(c), and was assigned Event Number 5450.

Licensee's Name: St. Luke's Regional Medical Center

Name of Prescribing Physician: Richard Hymas, MD, PhD

Brief Description of Event: A routine audit of written directives at St. Luke's Magic Valley Medical Center discovered a prescribed dose that did not match the dispensed dose by the radiopharmacy. The procedure occurred on February 20th, 2019. According to standard dosing protocols, the patient was to be injected with 83 microcuries of radium-dichloride (Xofigo). The correct amount was dispensed by the pharmacy and administered to the patient. The written directive, however, was prepared incorrectly and indicates a prescribed amount of 56 microcuries. The directive was prepared by and provided to the physician for review and signature. All subsequent documentation of the procedure indicates a value of 56 microcuries, while the patient received the intended 83 microcuries.

The difference in the incorrectly written prescribed dose and the correctly delivered dose is greater than 20%, and the dose delivered to the target organ/tissue (bone) was greater than 50 rem different from what the bone would have received according to the written directive. This meets the criteria for a medical event as defined by the NRC. However, the patient did receive the intended dose of (83 uCi) despite the clerical error of (56 uCi).

Why the Event Occurred: Standard practice for our written directives is to have the prescription written out according to the weight-based dosing protocols in advance of the procedure and signed by the physician. However, for this patient, the written directive was filled out on the day of the procedure based on the assayed amount of Xofigo. It is suspected that the dose was assayed using an incorrect setting on the dose calibrator, displaying a dose much less than was contained in the vial. The written directive was then filled out according to the incorrect assayed dose and provided to the physician for review and signature. All subsequent documentation of the dose then matched the written dose, as opposed to the actual administered dose.

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The Effect on Individuals who Received the Administration: Although the written directive was filled out incorrectly, the patient received the intended dose of approximately 83 microcuries. There are no effects to the patient from this event.

What Actions Have Been Taken to Prevent Recurrence: Staff members have been retrained in the appropriate completion of all written directives. All future written directives will receive the physician signature and approval prior to assaying the dose, based on the intended weight-based dosing protocols unless otherwise noted by the authorized physician user. Written directives will be audited quarterly by the Radiation Safety Officer or designee.

Notification of the Individual: The individual receiving this administration was not notified of the event. The intended dose was delivered to the patient and subsequent treatments have been administered correctly. This was a documentation and clerical error.

Should you need additional information regarding this request, please feel to call me at 208-381-3192, or by email at fullersc@slhs.org.

Sincerely,

Scott Fuller, MS, DABR
Radiation Safety Officer

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