

PROVIDENCE PARK HOSPITAL

April 19, 2018

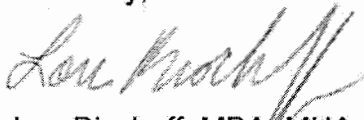
U.S. Nuclear Regulatory Commission Region III
Attention: Geoffrey Warren
2443 Warrenville Rd, Suite 210
Lisle, IL 60532-4352

Re: License No. 21-02802-03, Providence Hospital Event #53343

In accordance with 10CFR35.3045(d), we are providing a written report following the discovery of the medical event which was reported on April 19, 2018.

Thank you for your cooperation with this matter. If you have any questions or require additional information please contact our physicist, Michelle L. Kritzman, at (734) 662-3197.

Sincerely,



Lou Bischoff, MBA, MHA, CRA
Director, Imaging Services
Providence Hospital
Southfield, Michigan

Report and Notification of a Medical Event

Event Number: 53343

Licensee: Providence Hospital

Prescribing Physician: Roger L Gonda, M.D.

Event: On March 19, 2018, the Authorized User signed and dated a written directive for a patient to receive treatment for Xofigo using Radium-223 Dichloride for castration resistant prostate cancer. The prescribed dosage was 178.8 microcuries. The route was documented as "Oral".

On March 21, 2018, the Ra-223 Dichloride was assayed at 180 microcuries. The treatment was administered intravenously (IV) which is the appropriate administration route.

During the quarterly inspection, the medical physicist found the discrepancy in the route and reported the medical event to the NRC on April 18, 2018 at 13:14.

The referring physician and patient were notified by phone on April 18, 2018.

Why event occurred: The physician prescribed an "intravenous" injection of 178.8 microcuries of Radium-223 Dichloride. The nuclear medicine technologist did not properly write down the correct route on the written directive. The route was written in error as "Oral". The therapy was administered intravenously as intended; however, the route on the written directive was recorded incorrectly.

The effect on the individual who received the administration: There is no negative effect to the patient, since the proper route for this type of procedure was followed.

Action to prevent recurrence: A new written directive has been implemented. This has been included for review. The nuclear medicine technologists and Authorized Users were instructed on the new written directives. Review of the current policy and procedures were reviewed with staff.



Vikram A. Kinni, M.D.
Radiation Safety Officer



Lou Bischoff, MBA, MHA, CRA
Director, Imaging Services



Margaret Klobucar
Chief Operating Officer, Providence Hospital



WRITTEN DIRECTIVE - Xofigo

Patients Name: _____ Patient Id. Number: _____

RADIOPHARMACEUTICAL

Route

²²³Radium Dichloride

Intravenous (IV)

DESIRED PROCEDURE

Treatment Cycle (circle one) 1 2 3 4 5 6

_____ ²²³Radium Dichloride - castration-resistant prostate cancer

Prescribed Dosage: _____ **microcuries**

Signature of Authorized User: _____ Date: _____

PATIENT IDENTIFICATION

Patient Spelled Name: _____ Patient Stated Date of Birth: _____

Patient Stated S.S.N.: _____ Patient Wrist ID Identified: _____

Patient Presented Driver License (Number and State): _____

Technologist Signature: _____ Date: _____

DOSE DISPENSING RECORD

Radiopharmaceutical: _____ Prescribed Dosage: _____ **microcuries**

Dose Calibrator Assay: _____ Time: _____

Administration Time: _____

Technologist Signature: _____ Date: _____

Post-Administration

Dose Calibrator Assay: _____ Time: _____

Technologist Signature: _____ Date: _____

Written Revision:

Prescribed Dosage: _____ Route: _____

Authorized User Signature: _____ Date: _____