

April 26, 2018

MEMORANDUM TO: Docket File – Mercy Health St. Mary's, Grand Rapids, MI

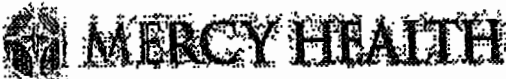
FROM: Geoffrey Warren, Senior Health Physicist

SUBJECT: Notice to next inspector

On February 21, 2018, the licensee reported a medical event concerning a therapy procedure using radium-223 dichloride. The NRC reviewed the report and determined that it did not constitute a medical event under 10 CFR 35.3045 because the procedure was performed in accordance with the written directive. As such, the licensee retracted the report and was not required to provide a written report. However, the dosage was miscalculated because it was based on an incorrect weight for the patient.

Attached are the event notification and a copy of the written directive and supporting documentation provided by the licensee. Please review this case during the next routine inspection.

Docket No. 030-08291
License No. 21-01078-01



Written Directive - Xofigo (Ra-223)

Patient Name: [Redacted] 1
 Date of Birth: [Redacted] 2
 MR Number: [Redacted] 3
 Referring Physician: [Redacted] 4

Date of Procedure: [Redacted] 5
 Time of Procedure: [Redacted] 6
 Treatment # of 6: [Redacted] 7

Patient's Weight (kg): [Redacted] 8
 Date Patient Was Weighed: [Redacted] 9
 NM Tech Initials & Date: [Redacted] 10 Verify Weight & Dose Calculation

Dose Calculation: Patient's Weight (kg) = 120 (110 kg)

Radiopharmaceutical: [Redacted] 11
 Route of Administration: [Redacted] 12
 Procedure: [Redacted] 13
 Procedure: [Redacted] 14

Authorized User: Dr. Spear, Malnor 15

Authorized Users for 10CFR35.300, 10CFR35.3 Tiedi, Paciorek, Malnor, Strauss, Williams, Rosol

Authorized User Signature: [Redacted] 16

Date & Time: [Redacted] 17

1) Nuc Med Tech completing form below. Initials, Date & Time: MP

2) Written Directive items (1 - 17) completed: Yes No

3) Hematological report attached and pass (within 4 weeks of procedure): Yes No

	Prior to first Injection	Subsequent Injections
Absolute Neutrophil (ANC)	≥ 1.5 (k/μL)	≥ 1 (k/μL)
Platelet Count	≥ 100 (k/μL)	≥ 50 (k/μL)
Hemoglobin	≥ 10 (g/dL)	Values should recover in 6-8 weeks

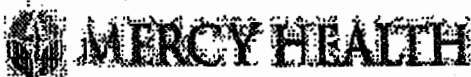
4) Chemotherapy Being Administered: (if yes, Xofigo should be discontinued) Yes No

5) Other Radiation Therapy Being Administered: (if yes, Xofigo should be discontinued) Yes No

- 6) Patient Questionnaire:
- a) Is the patient continent? Yes No
 - b) Is the patient able to care for themselves? Yes No
 - c) Does the patient care for or work with children? Yes No
 - d) Is the patient pregnant? (if yes, Xofigo should be discontinued) Yes No
 - e) Is the patient breast-feeding? Yes No
 - f) Can the patient follow the release instructions? Yes No
 - g) Comments:

7) Was the patient provided written instructions and counseling? Yes No

8) Patient's Weight (kg) 79.9



Written Directive - Xofigo (Ra-223)

Patient Name:
 Date of Birth:
 MR Number:

9) Nuc Med Tech Dose Verification:

Signature: [Signature]
 Date & Time: 1/23/18 1440
 Name: Lu Pl:yg

	Directive states	Verify	Error
Dose ($\pm 10\%$) μCi	119.1 μCi	119.0 μCi	0.0%
Radiopharmaceutical	Xofigo Ra-223	Ra-223	<input checked="" type="checkbox"/>

10) Patient identification method (circle two):

- a) patient states his or her name
- b) patient spells his or her name
- c) patient states his or her birthdate
- d) patient shows you a photo identification card
- e) check the wrist band

11) Patient ID & Time-out verification by:

Signature: [Signature]
 Date & Time: 1/23/18 15:00
 Name: Meredith Hague

	Directive states	Actual	Error
Route of Administration	IV	IV	0
Injection Time: Start to Finish	> 1 min	1:30	0
Measured Residual μCi	NA	0.0	NA
Delivered Dose ($\pm 10\%$) μCi	119.1 μCi	119 μCi (Verify Residual)	

12) Area survey:

Area Survey		
Hands	0.02	mR/h
Floor	0.02	mR/h
Table	0.02	mR/h
Chair	0.02	mR/h
Counter	0.02	mR/h

10 CFR 35.329(d) This record of the administered radiopharmaceutical dosage must be retained for a period of 3 years.

Organ	Mean (mGy/MBq)	Mean (rad/mCi)	Coefficient of Variation (%)
Osteogenic cells	1152	4263	41
Red marrow	139	514	41
LLI wall*	46	172	83
Colon*	38	142	56
ULI wall*	32	120	50
Small intestine wall	7.3	27	45
Urinary bladder wall	4.0	15	63
Kidneys	3.2	12	36
Liver	3.0	11	36
Heart wall	1.7	6.4	42
Lungs	1.2	4.5	48
Ovaries	0.49	1.8	40
Uterus	0.26	0.94	28
Gallbladder wall	0.23	0.85	14
Stomach wall	0.14	0.51	22
Adrenals	0.12	0.44	56
Muscle	0.12	0.44	41
Pancreas	0.11	0.41	43
Brain	0.10	0.37	80
Spleen	0.09	0.33	54
Testes	0.08	0.31	59
Skin	0.07	0.27	79
Thyroid	0.07	0.26	96
Thymus	0.06	0.21	109
Breasts	0.05	0.18	120
Whole Body	23	86	16

*LLI: lower large intestine; ULI: upper large intestine; colon dose = $0.57 \times \text{ULI dose} + 0.43 \times \text{LLI dose}^2$

3 DOSAGE FORMS AND STRENGTHS

Xofigo (radium Ra 223 dichloride injection) is available in single-use vials containing 6 mL of solution at a concentration of 1,100 kBq/mL (30 microcurie/mL) at the reference date with a total radioactivity of 6,600 kBq/vial (178 microcurie/vial) at the reference date.

4 CONTRAINDICATIONS

Xofigo is contraindicated in pregnancy.

Xofigo can cause fetal harm when administered to a pregnant woman based on its mechanism of action. Xofigo is not indicated for use in women. Xofigo is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus [see *Use in Specific Populations (8.1)*].



Mercy Health Saint Mary's
Nuclear Medicine and PET-CT
200 Jefferson SE
Grand Rapids, MI 49503
P 616.685.6205
F 616.685.8959

Fax

To: NRC From: Radiology Mercy Health Grand Rapids

Fax: 630-515-1259 Pages: 4 including cover

Phone: Date: 02/20/2018

Re: CC:

Urgent For Review Please Comment Please Reply Please Recycle

Please be aware that this facsimile may contain confidential or privileged information solely for the intended recipient. If you have received this facsimile in error, you are hereby notified to destroy all hard copies immediately and notify the sender by either phone or return fax.



**Reactor Operating Events
Event Notification Report**

***** Not For Public Distribution ***
Event Notification Report**

U.S. Nuclear Regulatory Commission - Operations Center
Event Reports For EN No (53224)
(May include 2-day hold)

53224

[TOP](#)

!!!! THIS EVENT HAS BEEN RETRACTED. THIS EVENT HAS BEEN RETRACTED !!!!	
Non-Agreement State	Event Number: 53224
Rep Org: SAINT MARY'S HEALTH CARE Licensee: SAINT MARY'S HEALTH CARE Region: 3 City: GRAND RAPIDS State: MI County: License #: 21-01078-01 Agreement: N Docket: NRC Notified By: TRISTON DOUGALL HQ OPS Officer: OSSY FONT	Notification Date: 02/21/2018 Notification Time: 15:33 [ET] Event Date: 02/20/2018 Event Time: 12:00 [EST] Last Update Date: 02/22/2018
Emergency Class: NON EMERGENCY 10 CFR Section: 35.3045(a)(1) - DOSE <> PRESCRIBED DOSAGE	Person (Organization): HIRONORI PETERSON (R3DO) NMSS_EVENTS_NOTIFICA (EMAI)

Event Text

DOSE TO PATIENT LESS THAN THE INTENDED DOSE

A patient was administered the radiopharmaceutical Xofigo which contains Radium Dichloride (Ra-223 CL2). The dosage is based on patient weight. The patient was administered 119.1 microCi. The patient was then weighed and found to weigh greater than 25 percent more than the weight used to calculate the dosage. This was the fourth treatment session of six prescribed. The referring physician's intended dose would have been 159 microCi, based on the patient's actual weight. This misadministration is being characterized as a personnel error.

The patient and the physician have been notified and treatment will continue.

A Medical Event may indicate potential problems in a medical facility's use of radioactive materials. It does not necessarily result in harm to the patient.

* * * RETRACTION ON 02/22/2018 AT 1541EST FROM TRISTON DOUGALL TO STEVEN VITTO * * *

The Licensee determined that the written directive was followed and therefore this event does not qualify as a misadministration.

Notified R3DO(Peterson) and NMSS Events Notification email.

Google™

Google Search

Search Internet Search www.nrc.gov

Information Security Reminder

This page on NRC's Internal Web site may contain sensitive information.
Check with the information owner before distributing outside the agency.

Last Updated on 3/26/2004 by NRRWebServices