



September 28, 2017

Nuclear Materials Licensing Branch
U.S Nuclear Regulatory Commission, Region IV
612 Lamar Boulevard, Suite 400
Arlington, TX 76011-4125

Subject: License: 25-15463-01 – Medical Event

Dear Janine:

Please find the attached documentation for a medical event at Kalispell Regional Medical Center, Kalispell Montana, License: 25-15463-01

Brief description of the event

Written Directive

Ordering physicians order

Calculated Dose – MPC, Medical Physics Consultants, Inc.

Medical Event

1 May 2017 - Medical event occurred

25 Sep 2017 15:00 - Medical event discovered

26 Sep 2017 11:30 - Medical event notification

1. RSO – Michael Henson, MD
2. AU – Patrick McDonnell, MD
3. Technologists Kathi Fairbank, Scott Edwards

26 Sep 2017 13:40 - Medical event call to NRC Operations Center
Medical Event Notification # 52993

26 Sep 2017 13:00 – Medical event notification to KRMC

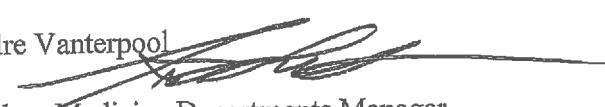
1. Administration Tyler Webber, Jeff Tintzman
2. Ordering physician – Jose Desouza, MD

The event occurred because of a transcription error in the written directive Authorized
User signature field.

There was no recordable effect on the patient who received the administration of I-131 because the dose that was given was the dose originally requested.

Actions taken to prevent recurrence - AU, 2 Technologists, departmental education and reorientation to the written directive. Three sets of eyes are to review the document for correct documentation before signing.

Andre Vanterpool



Nuclear Medicine Departments Manager
Administrative Radiation Safety Officer
W(406) 752-1770 C (406)212-6642
Kalispell Regional Medical Center

09/26/2017 16:52

On May 1, 2017, at Kalispell Regional Medical Center, a medical event occurred. Dr. DeSouza (Endocrinologist) prescribed a 20mci I-131 dose for his patient. The 20mci I-131 dose was ordered/ received and given to the patient as Dr. DeSouza prescribed. The written directive was filled out and signed by Dr. Mc Donnell, the authorized user, for 30mci I-131. This event occurred when the technologist, Kathi Fairbank, wrote 30mci I-131 instead of 20mci I-131 in the prescribed portion of the written directive that was signed by the authorized user. I believe this to be a sentinel event and has been reviewed/discussed with all individuals involved. Emails and discussion have occurred involving all staff, Radiologists (AU) and technologists whom will be more diligent when reviewing and signing written directives. Dr. DeSouza was notified on 9/26/2017 of the written directive error, and he has decided not to notify the patient as the dose given was what he prescribed.

This is written and submitted by Kathi Fairbank R.T(R)(CT)(CNMT).

WRITTEN DIRECTIVE

KALISPELL REGIONAL
MEDICAL CENTER

Name: [REDACTED]

Patient I.D. No: [REDACTED]

DATE OF TREATMENT: 5/1/17

Referring Physician: DeSouza

RADIOPHARMACEUTICAL

¹³¹I Sodium Iodide ⁸⁹Sr Chloride ¹⁵³Samarium Sodium ³²P

DESIRED PROCEDURE

^{Na131}Iodine Therapy for Hyperthyroidism ^{Na131}Iodine Whole Body Scan
 ⁸⁹Sr Therapy -palliation of osseous mets. ¹⁵³Sm Therapy -palliation of osseous mets
 ^{Na131}Iodine Substernal Thyroid Scan Na ¹³¹Iodine Therapy for Thyroid Cancer

PRESCRIBED DOSE: 30.0mCi I-131 ROUTE: Oral

SIGNATURE OF AUTHORIZED USER: [Signature] DATE: 5/1/17

PATIENT IDENTIFICATION

[Signature] Pt. Name Announced gc Spelling of Name ID Card
[REDACTED] Birth Date SS# Wrist Band Other

PREGNANCY / BREAST FEEDING STATUS

Negative pregnancy confirmed by: PG Test LMP N/A

Breast Feeding: Yes No N/A

DOSE DISPENSING RECORD

Administered Activity: 20.3mCi Radiopharmaceutical: I-131

Dosing Technologist Signature: [Signature] Date: 5-1-17

Verifying Technologist Signature: [Signature] Date: 5-1-17

Verify Assayed Dosage is within 10% of the prescribed dose: Yes No
If NO, Written Revision must be completed prior to administration.

WRITTEN REVISION:

PRESCRIBED DOSE: N/A ROUTE: N/A

AUTHORIZED USER: [Signature] DATE: N/A

Rx# [REDACTED]

¹³¹I Caps 2-1770287 1 Cap
20.00mCi 05-01-17@14:00
Exp:05-23-17 12:00 THYROID THERAPY
855-830-3423



Be: _____
le: _____
ian 60,000 and WBC count of less
hen platelet count is less than

Caution: Fed (USA) law prohibits dispensing without prescription.

1

NW Specialists

75 Claremont Street, Suite H
Kalispell, MT, 599013162
Tel: 406-751-5364 Fax: 406-751-5367

Jose de Souza, MD (NPI:1275534158)
Provider Code:

Endocrinology

Patient: [Redacted]
DOB: [Redacted] Sex: [Redacted] Phone: [Redacted]
Address: [Redacted]

Order Date: 04/27/2017 02:37 PM
Today: 04/28/2017 10:13 AM

Primary Insurance Name: [Redacted]
Insurance Address: [Redacted]
Subscriber Number: [Redacted]
Insured Name: [Redacted] Address: [Redacted]

DIAGNOSTIC IMAGING:

Code	Diagnostic Name	Assessment(s)	Notes	Instructions
NM: THYROID THERAPY I131 SUPPRESS		E05.90, Hyperthyroidism	de Souza, Jose 04/27/2017 02:40:17 PM > Please treat pt w/ 20 mCi of I 131 for Hyperthyroidism.	



Electronically Signed By: **Jose de Souza, MD**

Signature of Patient/Guardian

[Redacted Signature]



September 26, 2017

Andre Vanterpool, CNMT
 Nuclear Medicine
Kalispell Regional Medical Center
 310 Sunnyview Lane
 Kalispell, MT 59901

Dear Mr. Vanterpool:

This report is the calculated organ dose, effective dose, and effective dose equivalent for the following patient:

Patient Identifier: [REDACTED]
 Administration Date: 5/1/17
 Date Identified: 9/25/17
 Dose Intended: 30 mCi NaI-131
 Dose Received: 20.2 mCi NaI-131

Dose Calculations:

<u>Radiopharmaceutical</u>	<u>Administered Activity</u>	<u>Max Organ Absorbed Dose mGy/MBq</u>	<u>Total Absorbed Dose</u>
NaI-131 (Received)	747.4 MBq	4.30x10 ² mGy/MBq (Thyroid)	3.21x10 ⁵ mGy
NaI-131 (Intended)	1110 MBq	4.30x10 ² mGy/MBq (Thyroid)	4.77x10 ⁵ mGy
			156 Sv (difference)

<u>Radiopharmaceutical</u>	<u>Administered Activity</u>	<u>Effective Dose mSv/MBq</u>	<u>Total Effective Dose</u>
NaI-131 (Received)	747.4 MBq	2.20x10 ¹ mSv/MBq	1.64x10 ⁴ mSv
NaI-131 (Intended)	1110 MBq	2.20x10 ¹ mSv/MBq	2.44x10 ⁴ mSv
			8 Sv (difference)

214 E. Huron Street
 Ann Arbor, MI 48104
 (734) 662-9224 Fax
 (734) 662-3197

50 E. 91st Street, Suite 211
 Indianapolis, IN 46240
 (317) 581-1931 Fax
 (317) 581-1911

1731 E. Imperial Park Square
 Salt Lake City, UT 84106
 (734) 662-9224 Fax
 (801) 272-2952

N7375 Crystal Ridge Drive
 Beaver Dam, WI 53916
 (734) 662-9224 Fax
 (920) 885-9870

<u>Radiopharmaceutical</u>	<u>Administered Activity</u>	<u>Effective Dose Equivalent mSv/MBq</u>	<u>Total Effective Dose Equivalent</u>
Nal-131 (Received)	747.4 MBq	1.10x10 ⁰ mSv/MBq	8.22x10 ² mSv
Nal-131 (Intended)	1110 MBq	1.10x10 ⁰ mSv/MBq	1.22x10 ³ mSv
			3.99 Sv (difference)

Max organ dose and effective dose values used in this radiopharmaceutical dose estimate are taken from ICRP, 1998. Radiation Dose to Patients from Radiopharmaceuticals (Addendum to ICRP Publication 53). ICRP Publication 80. Ann. ICRP 28 (3). Effective Dose Equivalent values are taken from NRC, 1996, Radiation Dose Estimates for Radiopharmaceuticals, NUREC/CR-6345

This administration which occurred at your facility meets the definition of a *Medical Event* as defined by the Nuclear Regulatory Commission rule 10CFR35.3045 and must be reported to the NRC.

The report to the NRC must include:

1. A telephone call to the NRC operations center no later than the next calendar day after discovery of the medical event.
2. Written report that does **not** identify the patient within 15 days after discovery that includes:
 - a. Licensee name
 - b. Prescribing physician
 - c. Brief description of the event
 - d. Why the event occurred
 - e. The effect, if any, on the individual who received the administration
 - f. Actions taken to prevent recurrence
 - g. Certification that the individual was notified and if not why

The referring physician and individual shall be notified of the event within 24 hours of discovery. However, if in consultation with the referring physician it is determined that the physician will notify the patient or the physician determines that notifying the patient would be harmful, you do not have to notify the patient. The referring physician should also receive a copy of the report to the NRC with patient identifying information within 15 days.

If you have any questions concerning this report please contact me at (800)-321-2207.

Sincerely,



Adam Arndt, M.S., CHP, DABR
Medical Physicist