SAINT LOUIS
UNIVERSITY

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Office of Environmental Safety & Services
Environmental Safety: 314-977-8608
Radiation Safety: 314-977-8609

June 28, 2011

Mr. Robert Gattone (Robert.Gattone@nrc.gov)
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Subject: 15-Day Written Report for Medical Event Discovered on June 24, 2011;
NRC License No. 24-00196-07, Docket No. 030-11789

Dear Mr. Gattone,

In accordance with 10 CFR 35.3045, I am enclosing our 15-day report relative to the medical event that was discovered on June 24, 2011. As discussed during our telephone call on the Monday morning, June 27, 2011, I will be taking two weeks planned vacation beginning on Wednesday, June 29, 2011, making completion and submission of this 15-day report necessary at this time.

As communicated by separate email, it is my understanding that you will be arriving at Saint Louis University Hospital, Vista Avenue entrance, at 7:00 a.m. on Friday, July 1, 2011 for an on-site review of this event. As communicated in a separate email to you yesterday, June 28, 2011, arrangements have been made for our Associate Radiation Safety Officer and our Health Physicist to meet you.

If you have any questions regarding this report, or your review of this event following your visit later this week, I will be glad to discuss them with you upon my return to work on Wednesday, July 13, 2011. Meanwhile, you may contact our Associate Radiation Safety Officer for follow-up or to connect you to the appropriate person. This cover letter, and the enclosed report, are being provided to you by email. Please advise if we need to send a hard copy of the report to the Region III office.

Sincerely,

Mark Haenchen, M.S., J.D.
Director, Office of Environmental Health and Safety
and Radiation Safety Officer

enclosure

Cc: Philip Alderson, M.D., Vice President for Health Sciences
Raymond Tait, Ph.D., Vice President for Research
Paul Loewenstein, B.S., Chairman, Radiation Safety Committee
Medhat Osman, M.D., Chairman, Nuclear Medicine Division, Dept. of Radiology
Felicity Beckfield, M.S., Associate Radiation Safety Officer

NRC Medical Event – 15 Day Report

In accordance with 10 CFR 35.3045 (d) (1), this medical event written report is being submitted within 15 days of the discovery of the medical event:

i. **Licensee Name:** Saint Louis University

ii. **NRC License No.:** 24-00196-07

iii. **Name of the Prescribing Physician:** Medhat Osman, M.D.

iv. **Brief Description of the Event:** On June 21, 2011, a 115 mCi I-131 NaI therapy dose was administered to a patient instead of the intended 30 mCi I-131 NaI ablation dose. The discrepancy was discovered on June 24, 2011, when the referring physician inquired of the nuclear medicine technologist what the administered dose had been.

v. **Why the Event Occurred:** The Nuclear Medicine Technologist who was responsible for the transcription of the dose from the chart to the written directive overlooked the referring physician, Bruce Walz, M.D. (Radiation Medicine Department, Authorized User for 10 CFR 35.500, i.e., Brachytherapy) recommendation for a 30 mCi dose specified on two documents:

(1) A courtesy copy of a "consultation note" dated May 24, 2011 from Dr. Walz to a second referring physician group from another hospital regarding the treatment recommendation and plan for this patient *(see Appendix A of this report); and*
(2) A "Physician Orders" form dated June 16, 2011 signed by the referring physician, Dr. Walz *(see Appendix B of this report)*.

It is noteworthy that there was also a "Physician Orders" form dated May 24, 2011 signed by Dr. Walz that did not specify the dose *(see Appendix C of this report).* A third form, titled "Nuclear Medicine Service Requisition Form" *(see Appendix D of this report),* dated June 17, 2011, and also signed by Dr. Walz, did not specify the recommended dose.

The error resulted when the Nuclear Medicine Technologist noticed that a 125 mCi dose was recommended by Dr. Walz on page 2 of the consultation note (Appendix A), not recognizing that the higher 125 mCi therapy dose was recommended in lieu of a 30 mCi ablative dose, contingent upon TSH levels. The consultation note dated May 24, 2011 was not conclusive as to which dose would be administered, pending TSH results. However, the physician order dated June 16, 2011, which was overlooked by the Nuclear Medicine Technologist, provided a recommendation for a 30 mCi dose. Absent a specified dose recommendation on the Nuclear Medicine Service Requisition Form (Appendix C), the Nuclear Medicine Technologist relied on the information he had highlighted on the consultation note. These oversights led to the Nuclear Medicine Technologist ordering a 125 mCi dose (calculated to be 115 mCi at time of scheduled administration on June 21, 2011), and recording the 115 mCi activity on the written directive (titled "Quality Management Program – Prescription Form", *see Appendix E of this report)* for subsequent review and signature by the authorized user prescribing physician, Medhat Osman, M.D. (Nuclear Medicine Department, Authorized User for 10 CFR 35.100, 35.200, and 35.300, i.e. inclusive of radiopharmaceutical therapy).

The 115 mCi dose was within the normal range prescribed by Dr. Osman for a patient with this type of cancer, however, medical practice at this institution considers the recommendation of the referring physician, inclusive of the radiation dose if one is specified. Dr. Osman reviewed the written directive, after noting the highlighted 125 mCi *(115 mCi decayed for administration date)* dose information in the May 24, 2011 consultation note, previously referenced by the Nuclear Medicine Technologist, and approved the 115 mCi administration dose *(125 mCi to be ordered decayed to administration date activity of 115 mCi)*. Dr. Osman had also overlooked the physician order form from the referring physician dated June 16, 2011 which had recommended a 30 mCi dose. The 115 mCi dose was subsequently administered to the patient on June 21, 2011. It is noteworthy that the Nuclear Medicine Technologist has worked in the department for 35 years, has been extremely reliable, and never within that time frame had there been any reason to doubt the accuracy of information transcribed to the written directive form.

On June 24, 2011, during a follow-up conversation with Dr. Walz, a Nuclear Medicine Technologist had been asked what the final dose administered to the patient had been, and he expressed surprise that a 115 mCi dose had been administered. This led to further discussion with Dr. Osman, and the conclusion that a medical event may have occurred because even though a 125 mCi dose had been contemplated, and would possibly occur later, Dr. Osman's intent was to follow the recommendation of the referring physician, Dr. Walz.

vi. **The Effect, If Any , On The Individual(s) Who Received The Administration:** Although the dose differential between the AU prescribed and administered dose of 115 mCi is 85 mCi higher than the referring physician's recommended dose of 30 mCi, with a corresponding increase in dose to tissue or organ (e.g. bladder wall) exceeding 50 rems, and effective dose increase exceeding 5 rems, no harmful effects to the patient are expected. The dose administered was beneficial to the patient for treatment of the patient's thyroid cancer, and would have been prescribed in follow-up to the 30 mCi dose. *(See Appendix F, email from referring physician to Radiation Safety Officer.)*

vii. **What Actions, if any, have been taken or are planned to prevent recurrence:** This event was immediately reviewed upon discovery on June 24, 2011, continuing through a meeting held on June 27, 2011. Root causes of the event were reviewed and discussed, as well as corrective actions to prevent recurrence. In summary, three factors led to this medical event:

1. **Forms Used in the Business Practices:** There are three forms that are used in the business practices that were involved in this medical event, as specified below.

    a. "Physician Order Form" *(see Appendicies B and C)* – originated by the referring physician.
    b. "Nuclear Medicine Service Requisition Form" *(see Appendix D)* – originated by the referring physician.
    c. "Quality Management Program – Prescription Form", i.e. the written directive, completed by the Nuclear Medicine Technologist, reviewed and signed by the Nuclear Medicine Authorized User *(see Appendix E).*

    Assessment and Corrective Action: During the review of this event, it became clear that the forms either need to be used consistently, i.e. always specify the recommended

dose (item a. and b. above) or eliminate one of the forms (item a.) It has been agreed that all three forms serve a useful business need. Moving forward, the "Physician Order Form" will continue to be used, but will not be reviewed by Nuclear Medicine staff for a recommended dose from the referring physician. Instead, the referring physician must specify a recommended dose on the "Nuclear Medicine Services Requisition Form". If a recommended dose is absent from this form, the assigned Nuclear Medicine Technologist and/or the Nuclear Medicine Physician Authorized User will consult with the referring physician to determine whether or not they have a recommended dose. The recommended dose will then be specified on the requisition form. If the referring physician does not have a recommendation, the Nuclear Medicine Physician Authorized User will determine the prescribed dose to be entered on the written directive (item c. above.)

2. **Review of documentation by Nuclear Medicine Technologists transcribing recommended dose to Written Directive:** Following the procedures outlined in Corrective Action No. 1 above, the Nuclear Medicine Technologist will be limited to using only the completed "Nuclear Medicine Requisition Form" to determine the referring physician recommended dose. Absent a recommended dose, the referring physician will be consulted, or the Nuclear Medicine Authorized User.

3. **Review of Written Directive by Nuclear Medicine Authorized User:** Following the procedures outlined in Corrective Action No. 1 above, the Nuclear Medicine Authorized User will review the written directive (i.e." Quality Management Program Prescription Form"), inclusive of the specified dose recorded by the Nuclear Medicine Technologist, and compare against the "Nuclear Medicine Requisition Form" to determine consistency with the referring physician recommended dose. Absent a recommended dose, the Nuclear Medicine Authorized User will consult with the referring physician.

viii. **Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not why not:** The Nuclear Medicine Physician Authorized User, Dr. Osman consulted with the referring physician, Dr. Walz on June 24, 2011 during the discovery of this event. The patient, already scheduled to be seen on June 24, 2011 by the referring physician, was notified of the medical event on that date. Dr. Walz documented his follow-up communications in a "Follow-up Note" dated June 24, 2011 to the outside hospital referring physician group. *(See Appendix G).*

Respectfully Submitted: Mark Haenchen, M.S., J.D.
Director, Office of Environmental Health and Safety
and Radiation Safety Officer - NRC
Saint Louis University

Dated: June28, 2011

APPENDIX A

SLUCare®
The Physicians of
Saint Louis University

Department of Radiation Oncology

3635 Vista Ave at Grand Blvd
St. Louis, MO 63110-0250
Phone: 314-577-8815
Fax: 314-268-5114
Bruce J. Walz, M.D., F.A.C.R.
MacDonald B. Logie, M.D., F.A.C.R.
John J. Dombrowski, M.D., Ph.D.
Julie Dawson, Ph.D., F.A.A.P.M.

May 24, 2011 **CONSULTATION NOTE**

RE: [redacted] [redacted]
DOB: [redacted]
Phone number [redacted]
significant other [redacted] cellphone [redacted]

REFERRING PHYSICIANS: George Thampy, M.D., Ph.D. (Fax 543-5298)
Paul Garvin, M.D. (Fax 525-4323)
Mark Scheperle, M.D.
Suzanne Mahon, RN. Ph.D., Genetic Counselor

DIAGNOSIS: Follicular variant papillary thyroid cancer, pT3 Nx Mx.

HISTORY OF PRESENT ILLNESS: Mr. [redacted] is a 34-year-old district loss prevention manager for [redacted] the father of children 3 years and 5 months old, referred to us by Dr. Thampy anticipating radioiodine treatment after thyroidectomy for papillary thyroid cancer.

History is primarily from the patient himself who seemed to give excellent history, as well as Dr. Thampy's very complete note, and the pathology report from St. Anthony's Medical Center.

In retrospect, the patient has had minor dysphagia with difficulty swallowing liquids, gradually getting worse over a long period of time. He noticed no weight loss. Ms. [redacted] indicates that he had been snoring very loudly.

The patient developed what he thought was sinus infection, and saw a nurse at a Walgreen's Clinic. She apparently palpated his neck, and he was promptly referred to Dr. Scheperle and on to Dr. Thampy. The biopsy showed thyroid cancer, and on May 9, 2011, the patient underwent a total thyroidectomy. The specimen weighed 128 g, and there was a 9 cm mass on the left. There were areas that were suspicious for vascular invasion, but it was not definitive. There was no extrathyroidal extension. No parathyroid tissue was seen.

Postoperative recovery has been uneventful. The patient has not had any muscle problems. He notices his voice cannot hit high notes as well as he used to. his voice is otherwise normal. There no longer is any dysphagia. He has had minor secretions.

PAST HISTORY: Noncontributory. The patient has no history of cancer. No history of radiation exposure. No chemotherapy. No history of heart attack, stroke, diabetes mellitus, high blood pressure, or lung problems. The patient may have had asthma as a child many years ago. No history of liver, kidney, or blood diseases. No depression or psychiatric illness. No skin diseases. No drug allergies.

REVIEW OF SYSTEMS: Occasional headaches, which are mostly frontal, sometimes more toward the vertex, and may be associated with stress. Good hearing and balance. Normal eyesight. As stated, no dysphagia or odynophagia. The patient has cough productive of nasal secretions. No shortness of breath or chest pain (in retrospect, the patient did have a little bit of dyspnea preoperatively).

Bowels are normal without blood or mucus. No recent change. Normal urinary function. No aches or pains suggesting metastases.

FAMILY HISTORY: Strongly positive for cancer. His mother had breast cancer, and a sister died from breast cancer, and another sister is in remission who has breast cancer he states. One aunt had lung cancer he states, and she was a nonsmoker. One grandfather died of lung cancer, and another colon cancer.

RADIOGRAPHIC STUDIES: In view of the preop ultrasound, he describes the tumor.

MEDICATIONS: Cytomel, Caltrate, and vitamin D.

PERTINENT PHYSICAL EXAMINATION: Robustly healthy appearing gentleman who seemed to be approximately stated age of 34 years. He is alert and cooperative, obviously quite intelligent. The patient states he is 6'1" tall, and weight is 198.8 pounds. Afebrile. Normal respirations. Blood pressure is 129/82 left arm sitting, and his pulse is regular at 96 beats per minute. Oxygen saturation is 96% on room air.

No scleral icterus. No eye signs. There is a small incision in the neck, still covered with Steri-Strips. It appears to be healing normally. The neck is normal to palpation. The patient has a few respiratory moans in both bases, cleared with cough. Lungs are otherwise normal. Heart rate is regular. No palpable abdominal masses or organs. No edema of lower extremities. Normal strength in upper and lower extremities.

IMPRESSION: Thyroid cancer, post total thyroidectomy.

RECOMMENDATION AND PLAN: Therapeutic I-131.

We have made the following schedule. The patient is to stop his T3 on Friday, June 3, 2011 (he and Ms. [redacted] have a wedding to attend the following weekend, he indicated he may be "dragging his anchor"). He is to see Dr. Thampy on June 13, 2011, and I would recommend TSH, as well as T3 and T4 studies. If the TSH is up, and the T3 and T4 are quite low, we will plan for a therapeutic dose with iodine on Thursday, June 16, 2011, giving approximately 125 mCi. I recommended he take off from work on Thursday, and return on Monday, June 20, 2011 for scanning and to see me.

If there is still a significant thyroid function after the patient comes off his T3, we might consider an ablative dose for about 30 mCi rather than therapeutic dose, anticipating the therapeutic dose to follow later.

I explained situation in great detail to the patient in the presence of his companion. I indicated there is risk of carcinogenesis, leukemogenesis from the radiation, as well as injury to the bone marrow, kidney, lungs, etc. He has not planned to have any further children, but if he did, there could be mutations in future generations.

I also reviewed radiation safety precautions, and since they have small children, the patient will plan to be away from the household for about a week. I reviewed radiation sanitation procedures in detail.

Mr. [redacted] and Ms [redacted] have signed the informed consent; the patient is scheduled as above.

ADDENDUM: After the patient departed, I spoke with Dr. Thampy who indicated that the tumor had grown rapidly from the time he first saw him until the operation was performed. He asked that we have genetic counseling, that specific studies be done for markers for thyroid cancer. I will send a note to Dr. Mahon asking her to check specifically.

Thank you for referring us this fine gentleman.

Bruce J. Waltz, M.D., F.A.C.R.
Professor & Director

BJW/sd

APPENDIX B

Saint Louis University Hospital

Do Not Use the Following Abbreviations in your Orders:
U, IU, QD, Q.D., q.d., Q.O.D., q.o.d., qod, MS, MSO4, MqSO4, X.0mg, .Xmg, ug, cc, @, >, <, x ___d
Orders containing these unapproved abbreviations will not be processed

[redacted]

ALLERGIES:

DATE	TIME		HT.	WT.	ALL MEDICATIONS DISPENSED IN ACCORDANCE WITH HOSPITAL FORMULARY
		NM BSGI Labs/notes			VO/TO READ BACK INITIAL
6/6/11		[redacted] 374 [redacted]			
		(1) For I-131 treatment on Monday 30mCi ± 3			
		(2) Records to Dr Nguyen			
		(3) Pt. notify pt re time (a) Come here first & (b) I will escort to Nuc Med			
		(4) Have slides come from St Anthony's (YP) (W)			

PHYSICIAN ORDERS
ALL PHYSICIAN'S ORDERS MUST BE WRITTEN IN INK
(DATED, TIMED & SIGNED)

IF NO NUMBER SHOWING.
PLEASE USE NEW ORDER SHEET.

092510 (5/10)
46825

APPENDIX C

Saint Louis University Hospital

Do Not Use the Following Abbreviations in your Orders:
U, IU, QD, Q.D., q.d., Q.O.D., q.o.d., qod, MS, MSO4, MgSO4, X.0mg, .Xmg, ug, cc, @, >, <, x___d
Orders containing these unapproved abbreviations will not be processed

[redacted]

ALLERGIES:	HT.	WT.	ALL MEDICATIONS DISPENSED IN ACCORDANCE WITH HOSPITAL FORMULARY

DATE	TIME		VO/TO READ BACK INITIAL
5/24/11 10:30 am		[redacted]	
		Blood work Dr Thompson 6/13 - check next day	up
		Tentatively [illegible] - Thur 6/16	back 6/14
		✓ Slides from St Anthony's	
		✓ Appt smoking cessation	
		✓ Dr S. Mahon - genetic counseling	
		✓ 577-8854	
		✓ Recent - now	
		[illegible signature]	

PHYSICIAN ORDERS
ALL PHYSICIAN'S ORDERS MUST BE WRITTEN IN INK (DATED, TIMED & SIGNED)

IF NO NUMBER SHOWING. PLEASE USE NEW ORDER SHEET.

[redacted] 05/24/2011
ACCT# [redacted] M 34Y
Walz, Bruce J. MR:M001048513
ST LOUIS UNIVERSITY HOSPITAL

092510 (6/10)

APPENDIX D

Saint Louis University Hospital

NUCLEAR MEDICINE SERVICE REQUISITION FORM

Scheduling - Phone 314-577-8022 FAX 314-268-5539

Physician Name (Please): Date of Order: 6/17/11

Physician Signature is required for services to be rendered

Physician Signature: X DOB Module:

Patient: Office Phone: Office Fax:

D.O.B: 05/24/2011 Insurance:

M 34Y Ins. Authorization #:

PCP: Walz, Bruce J. MRN#001048513 ST LOUIS UNIVERSITY HOSPITAL

Medicare Regulations

Medicare regulations require the tests to be medically necessary for the diagnosis and treatment of the patient to qualify for reimbursement from the program. The physician must be treating the patient in connection with the diagnosis or complaints listed and this information must accurately reflect the medical reasons for requesting these tests. The medical necessity of each test ordered on this requisition must be documented in the patient's medical record. Tests ordered for the purpose of screenings or which the physician believes to be appropriate even if the payor may not allow reimbursement, may not be billed to Medicare except for the purpose of receiving a denial.

REASON FOR NUCLEAR MEDICINE EXAM / SPECIAL INSTRUCTIONS

Thyroid cancer

X	CPT	Cardiovascular System
	78451	Myocardial perfusion imaging; tomographic (SPECT), single study at rest or stress (exercise and/or pharmacologic), with or without quantification. Thallium Viability
	78452	Myocardial perfusion imaging ; tomographic (SPECT), multiple studies, at rest and/or stress (exercise and/or pharmacologic) and redistribution and/or rest injection, with or without quantification
	78453	Myocardial perfusion imaging; planar, Single study (rest or stress)
	78454	Multiple studies, at rest and/or rest (exercise or pharmacologic) and/or redistribution
	78473	MUGA, cardiac blood pool imaging, multiple studies
	78481	Cardiac blood pool imaging, FIRST PASS (gated)(rest single study, at rest or with stress

X	CPT	Respiratory System
	78580	Perfusion Lung Scan (Particulate)
	78585	Pulmonary perfusion imaging, particulate, with ventilation; rebreathing and washout, with or without single breath, VQ.
	78596	Pulmonary quantitative differential function (ventilation/perfusion) study

X	CPT	Musculoskeletal System
	78300	Bone and/or joint imaging; limited areas
	78305	Bone and/or joint imaging; whole body
	78315	Bone and/or joint imaging; three phase study
	78320	Bone and/or joint imaging; tomographic (SPECT)

X	CPT	Nervous System
	78607	Brain imaging, complete procedure; tomographic (SPECT)
	78630	Cerebrospinal fluid flow, imaging; CISTERNOGRAPHY

X	CPT	Hematologic, Reticuloendothelial and Lymphatic System
	78195	Lymphatics and lymph node imaging (Lymphoscintigraphy)

X	CPT	Other Procedures
	78801	I123 (MIBG)
	78802	Localization of tumor IV8 (OCTREOSCAN)
	78803	Radiopharmaceutical Localization of Tumor (SPECT) - Gallf
	78804	Radiopharmaceutical localization of tumor; whole body 2 OR MORE DAYS imaging (In-111 ZEVALIN)
	78403	Zevalin Therapy (Y-90)
	78805	Radiopharmaceutical localization of inflammatory process; limited area (In-111)
	78806	Radiopharmaceutical localization of inflammatory process; whole body (In-111)
	79101	Radiopharmaceutical Therapy (Unlisted)

X	CPT	Genitourinary System
	78709	Kidney Imaging (DMSA)
	78707	Kidney imaging with vascular flow and function; single study without pharmacological intervention (DIATRIDTPA)
	78708	Kidney imaging w/ pharmacological intervention (Lasix or Captopril)
	78710	Kidney imaging, tomographic (SPECT)
	78725	Kidney Function Study, Non-Imaging Radioisotopic Study (GFR)

X	CPT	Endocrine System
	78001	Thyroid Uptake ONLY (RAIU)
	78007	Thyroid Imaging with Uptake (RAIU & SCAN)
	78010	Thyroid Imaging ONLY
	78015	I123 / I131 Thyroid WB SCAN
	78070	Parathyroid Imaging
X	79005	Radiopharmaceutical Therapy, Hyperthyroidism/Thyroid carcinoma (I131's)

X	CPT	Gastrointestinal System
	78200	Liver Imaging (SPECT) - Hemangioma
	78215	Liver/Spleen Imaging (Static Only)
	78216	Liver/Spleen Imaging (with vascular flow)
	78223	Hepatobiliary ductal system imaging, incl. Gallbladder, w/ or w/o pharmacologic intervention, w/ or w/o quantitative measurement of gallbladder function (DISIDA/HIDA)
	78258	Esophageal motility
	78262	Gastroesophageal Reflux Study
	78264	Gastric emptying study
	78267	Urea breath test, C-14; acquisition for analysis
	78278	Acute GASTROINTESTINAL BLOOD LOSS IMAGING (GI Bleed)
	78290	Intestine imaging (e.g. ectopic gastric mucosa, Meckel's localization, volvulus)

Findings of Supporting Imaging or Pathology must be faxed to 314-268-5539

APPENDIX E

Saint Louis
University Hospital

Nuclear Medicine Division - Saint Louis University Hospital
QUALITY MANAGEMENT PROGRAM - PRESCRIPTION FORM

PATIENT IDENTIFICATION {Patient No. [redacted]}

[redacted] (LAST NAME) [redacted] (FIRST NAME) [redacted] (M.I.) [redacted] (MO/DA/YR)

PROCEDURE AND PRESCRIPTION INFORMATION

PROCEDURE:

[ ] Hyperthyroid
[ ] Total Body Imaging
[ ] Thyroid Ablation
[✓] Thyroid Cancer Treatment
[ ] Radionuclide Synovectomy
[ ] Relief Of Bone Pain
[ ] Non-Hodgkins Lymphoma Therapy
[ ] Other; specify: _____

RADIOPHARMACEUTICAL & ROUTE OF ADMINISTRATION:

[✓] I-131 sodium iodide; PO
[ ] P-32 chromic phosphate; IC
[ ] P-32 sodium phosphate; IV
[ ] Sm-153 Quadramet; IV
[ ] Sr-89 strontium chloride; IV
[ ] Y-90 Zevalin therapy
[ ] Other; specify: _____

DOSE: 115 mCi

APPROVED BY: _____ (Authorized User Signature)

PRINTED NAME: [ ] Nghi Nguyen, M.D.
[✓] Medhat Osman, M.D. [ ] TBA
[ ] Other; specify: _____

DATE APPROVED BY AUTHORIZED USER: 6.20.11 (MO/DA/YR)

PATIENT I.D. & PREGNANCY VERIFICATIONS

PATIENT IDENTIFICATION VERIFICATION: (Check TWO):

[✓] Patient asked his/her name; matches record.
[✓] Patient I.D. bracelet matches record.
[✓] D.O.B. (Date Of Birth) per patient matches record.
[ ] **Patient is non-responsive or unreliable; specify sources of I.D. verification:**

_____

_____

PREGNANCY STATUS VERIFICATION:

[ ] Patient is not pregnant because: _____

_____

_____

[ ] Patient is not breast feeding.

[ ] **If pregnancy status is uncertain, results of HCG:**
[ ] negative (not pregnant)
[ ] **positive (pregnant)**

[✓] Not applicable; male patient

VERIFICATION OF PRESCRIPTION, MEASURED DOSE, & PATIENT IDENTITY

The patient named above has been correctly identified, the radiopharmaceutical has been correctly identified, the measured dose is within 10% of the prescribed dose and the dose was administered according to the prescription directions.

6.21.11 (Date of Administration)

(1) **Dose Administrant:** _____ (Signature of Nuc. Med. Physician, Tech. or Nuc. Pharmacist)

(2) **Reviewer/Witness:** _____ (Signature of 2nd N.M. Tech., Physician, or Nuc. Pharmacist)

APPENDIX F

SAINT LOUIS UNIVERSITY

Mark Haenchen <haenchen@slu.edu>

Therapeutic I-131 dose

Bruce Walz <walzbj@slu.edu> **Mon, Jun 27, 2011 at 8:58 AM**
To: "Mark Haenchen,M.S.,J.D." <haenchen@slu.edu>, "Robichaux, Hugh" <JERRY.Robichaux@tenethealth.com>, "Medhat M. Osman, M.S.,M.D.,Ph.D." <mosman@slu.edu>

Mark -
This morning, I spoke personally c the referring Endocrinologist and informed him of the 115 mCi dose. Our plan was eventually to give a therapeutic dose of I-131, but start c an ablative dose. Many practitioners would have given the therapeutic dose at this point in the pt's course. No harm has been done, though technically this is a misadministration.
Bruce

--
Bruce J. Walz, M.D., F.A.C.R.
Professor and Chair, Radiation Oncology
St. Louis University School of Medicine
Director, Radiation Medicine
St.Louis University Hospital
3635 Vista
St.Louis, Missouri 63110
voice 314-577-8815, fax 314-268-5113

APPENDIX G

SLUCare®
The Physicians of
Saint Louis University

Department of Radiation Oncology

3635 Vista Ave at Grand Blvd
St. Louis, MO 63110-0250
Phone: 314-577-8815
Fax: 314-268-5113
Bruce J. Walz, M.D., F.A.C.R.
MacDonald B. Logie, M.D., F.A.C.R.
John J. Dombrowski, M.D., Ph.D.
Julie Dawson, Ph.D.

June 24, 2011 FOLLOW-UP NOTE

RE: [redacted] [redacted]
DOB: [redacted]
Phone number [redacted]
significant other [redacted] cellphone [redacted]

REFERRING PHYSICIANS: George Thampy, M.D., Ph.D. (Fax 543-5298)
Paul Garvin, M.D. (Fax 525-4323)
Mark Scheperle, M.D.
Suzanne Mahon, RN. Ph.D., Genetic Counselor
(the patient has not yet seen Dr. Mahon)

DIAGNOSIS: Follicular variant papillary thyroid cancer, clinical stage pT3 NX MX.

Please see note of May 24, 2011.

We measured Mr. [redacted] thyroid functions, and after the thyroidectomy, his free T4 was quite low at 0.7 mg/dL (0.8 normal maximum), but his free T3 was 3.73 pg/mL, in the low normal range. His thyroglobulin remains elevated at 31.6, which is the top of the normal maximum range. His thyroglobulin antibodies were negative. His TSH was 6.66 units, above the normal maximum of 4.68. These tests were all done on June 13, 2011.

It was my intent to administer an ablative dose of 30 mCi I-131 to the patient.

However, the patient received a therapeutic dose of 115 mCi of I-131 on June 21, 2011.

He returned today for a thyroid scan. He is feeling pretty good, no particular side effects. He has isolated himself from his family to a great deal.

A scan was performed, and I am awaiting the "official" report from nuclear medicine, but the thyroid bed shows up very intensely with an area off to the left side, and I believe inferiorly which has moderate uptake. I do not see any extra-cervical "spots".

Mr. [redacted] returned to the department afterwards, and I indicated to him that he had received a therapeutic dose of iodine. I pointed out that many practitioners would at this point in his course have given a similar sort of dose. We measured the output of radiation from his body at 1 meter, registered 3.4 mR/hr.

Since we prefer people to be below 0.2 mR/hr when "mixing with other people", I advised him to keep a good distance away from his significant other, and good deal of distance from his children, who are six months and three years old.

The patient is to return again in four days for remeasurement, asking him to drink lot of fluids. The long-term plan is to repeat the thyroid function, TSH, thyroglobulin, antithyroglobulin in several months. The patient will be seeing Dr. Thampy in three days.

Mr. [redacted] may call me if he has any questions or problems, and I plan to see him again in four days,on the morning of Tuesday, June 28, 2011

I called Dr. Thampy, the patient's endocrinologist, to inform about the dose of I-131, but Dr. Thampy is not available. I anticipate speaking with him on Monday, June 27, 2011.

Thank you for referring us this very fine gentleman.

6/27/11. Dr Thampy attempted to call me on 6/24/11. We spoke that morning.

Bruce J. Walz, M.D., F.A.C.R.
Professor & Director

BJW/sd

TSV REF#: 624-n-slu-rad-BWAL3290.doc