## Gattone, Robert

**From:** Mark Haenchen [haenchen@slu.edu]
**Sent:** Wednesday, July 27, 2011 9:07 PM
**To:** Gattone, Robert
**Cc:** Paul Loewenstein, B.S.
**Subject:** Fwd: Follow-up Information Relative to NRC July 1, 2011 Visit to Saint Louis University Hospital
**Attachments:** No 1 - Amended 15-Day Report.pdf; No 2 - Copy of Posted NucMed Permit 2008-08-13.pdf; No 3 - RSC Minutes 2002-09-26 Exerpt.pdf; No 4 - RSC Minutes 2008-06-11 Exerpt.pdf; No 5 - Cover Letter to Chief Med Officer 2002-09-23.pdf; No 6 - Cover Letter and NM Permit 2002-09-26.pdf

Dear Bob,

I am reforwarding this message, but removing attachments No. 7 and No. 8, which I will try to forward separately.

- Mark

---------- Forwarded message ----------
From: **Mark Haenchen** <haenchen@slu.edu>
Date: Wed, Jul 27, 2011 at 8:56 PM
Subject: Follow-up Information Relative to NRC July 1, 2011 Visit to Saint Louis University Hospital
To: Bob Gattone <Robert.Gattone@nrc.gov>
Cc: "Paul Loewenstein, B.S." <loewenpm@slu.edu>

Dear Bob,

Per your request, I am forwarding additional information, pursuant to your exit meeting follow-up phone call when we spoke by telephone on Monday, July 18, 2011, addressing the following:

1. Addendum to the 15-day report to clarify corrective action.
    - **PDF Attachment No. 1** (Changes were made to the first paragraph on page 3; changes have been italicized).
2. Documentation of the RSC's specific authorizations for Dr. Osman and Dr. Nguyen for 10CFR35.100, 200, 300, and 500.
    - **PDF Attachment No. 2:** Copy of Nuclear Medicine Permit following addition of Dr. Nguyen and another physician (dated August 2008).
    - **PDF Attachment No. 3:** Copy of relevant section pages of RSC minutes (page 2 of minutes and 2nd page of Appendix A (summary table) for September 2002 RSC Meeting (Dr. Osman approval).
    - **PDF Attachment No. 4:** Copy of relevant section pages of RSC minutes (page 3 of minutes and 2nd page of Appendix A (summary table) for June 11, 2008 RSC Meeting (Dr. Nguyen approval).
    - **PDF Attachment No. 5:** Copy of letter to Chief Medical Officer dated September 23, 2002 providing additional details regarding the RSC specific authorizations. (This letter accompanied a copy of the packet provided in reference to No. 3 below (PDF Attachment No. 7), less the cover page that specifies "Section 5".)

- **PDF Attachment No. 6:** Copy of the cover letter that accompanied distribution of reduced copies of the 11"x 17" updated Nuclear Medicine Permit (also included), and referenced in Attachment No. 5.

3. Records for Dr. Osman's training and experience, etc. relative to 35.390.
   - **PDF Attachment No. 7:** Copy of Application Packet Materials, as provided to RSC and as filed with RSC minutes for September 26, 2002 RSC meeting.
   - **PDF Attachment No. 8:** Copy of Nuclear Medicine Board Certification for Dr. Osman.

Please contact me if you have any questions, need additional information or any clarifications.

Sincerely,
- Mark

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(and Radiation Safety Officer - NRC)
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**NRC Medical Event – 15 Day Report**
**(Amended 07/26/2011)**

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 *may* 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 *may* consult with the referring physician to determine whether or not they have a recommended dose. *Referring Physician recommended doses may be considered by the Nuclear Medicine Physician Authorized User, but the prescribed dose specified on the written directive (item c.) remains the full responsibility of the Nuclear Medicine Physician Authorized User. Whether or not a referring physician specifies a recommended dose, only* 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 (Amended, July 26, 2011)