August 26, 2011

NMED 110320 (Closed)

Mr. Lawrence J. Biondi, S.J., President
Saint Louis University
President's Office
DuBourg Hall, Room 206
221 N. Grand Boulevard
St. Louis, MO 63103

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 030-11789/11-001(DNMS) – SAINT LOUIS UNIVERSITY

Dear Mr. Biondi:

On July 1, 2011, with continued in-office review through July 28, 2011, two Nuclear Regulatory Commission (NRC) inspectors conducted a reactive inspection at Saint Louis University in St. Louis, Missouri. The in-office review included, among other things, receipt and review of qualification records for an authorized user and records of the Radiation Safety Committee's approval of two authorized users. The purpose of this inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for a medical event that your staff reported to the NRC on June 24, 2011. The inspectors determined a medical event did not occur. On July 5, 2011, the licensee retracted the June 24, notification of a medical event. The findings of the inspection were discussed with members of your staff at a preliminary exit meeting on July 1, 2011, and at a final, telephonic exit meeting with Mark Haenchen, Radiation Safety Officer, on August 4, 2011. The enclosed report presents the results of this inspection.

During this inspection, the NRC staff examined activities conducted under your license as they relate to public health and safety to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, no violations of NRC regulatory requirements were identified. In addition, the inspectors determined that, although the referring physician's intended dosage was not administered to the patient, the reported medical event was not a "medical event" as defined in Title 10 of the Code of Federal Regulations (CFR) 35.2 because the administered dosage was in accordance with the dosage prescribed on the written directive.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's

Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Sincerely,

/RA Pat Louden for/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-11789
License No. 24-00196-07

Enclosure:
Inspection Report No. 030-11789/11-001(DNMS)

cc w/encl: Mark Haenchen, Radiation Safety Officer
State of Missouri

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cc w/encl: Mark Haenchen, Radiation Safety Officer
State of Missouri

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NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-11789
License No.:	24-00196-07
EA No.:	N/A
Report No.:	030-11789/11-001(DNMS)
Licensee:	Saint Louis University
Location:	Saint Louis University Hospital 3635 Vista Avenue, St. Louis, Missouri
Dates of Inspection:	July 1, 2011, with continued in-office review through July 28, 2011
Exit Meeting:	August 4, 2011
Inspectors:	Robert G. Gattone, Jr., Senior Health Physicist Andrew M. Bramnik, Health Physicist
Reviewed By:	Tamara E. Bloomer, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Saint Louis University
St. Louis, Missouri
Inspection Report No. 030-11789/11-001(DNMS)

U.S. Nuclear Regulatory Commission (NRC) inspectors conducted a reactive inspection on July 1, 2011, with continued in-office review through July 28, 2011, to review the events and circumstances associated with the licensee's notification of a medical event to the NRC on June 24, 2011. The inspectors determined that a medical event did not occur because, although the administered dosage was not what the referring physician intended, it was in accordance with the dosage prescribed on the written directive. The authorized user (AU) typically would administer the dosage of iodine-131 to a patient as recommended by the referring physician. However, the authorized user prescribed 115 millicuries of iodine-131 on the written directive, and 115 millicuries of iodine-131 was administered to the patient. The AU and the referring physician determined that there would be no adverse consequences to the patient from the unintended dosage.

The root cause of the unintended dosage was the Nuclear Medicine Technologist (NMT) and AU's failure to completely read the referring physician's Consultation Note that included the recommended dosage. The contributing factors were: (1) the NMT obtained the dosage to order from the referring physician rather than the AU; (2) the NMT ordered the dosage without verifying it with the AU; and (3) the referring physician was unavailable to observe the preparation and administration of the dosage, which was a departure from the physician's normal practice.

No violations of NRC regulatory requirements were identified.

To prevent unintended dosages of iodine-131 from being administered to patients, the licensee: (1) required that referring physicians may specify a recommended dosage on the "Nuclear Medicine Services Requisition Form" and, if a recommended dosage is absent from the form, the assigned NMT or AU may consult with the referring physician; (2) required NMTs to use only the completed Nuclear Medicine Services Requisition Form to determine the referring physician's recommended dosage; (3) clarified that, although AUs may consult with the referring physician to determine whether or not they have a recommended dosage, the prescribed dosage in the written directive remains the full responsibility of the AU; (4) clarified that, whether or not a referring physician specifies a recommended dosage, only the AU will determine the prescribed dosage to be entered on the written directive; and (5) required the AUs to review the written directive, including the specified dosage recorded by the NMT, and compare it against the Nuclear Medicine Services Requisition Form to verify consistency with the referring physician's recommended dosage.

Report Details

1 Program Scope and Inspection History

The NRC License Number 24-00196-07 authorizes Saint Louis University (licensee) to use, in part, byproduct material for in-vitro studies, diagnostic and therapeutic nuclear medicine, manual brachytherapy, and blood irradiation. As of July 1, 2011, the licensee performed about three hyperthyroidism treatments per month using about 10 to 20 millicuries of iodine-131 in capsule form. In addition, the licensee performed about one thyroid cancer treatment per month using about 120-125 millicuries of iodine-131 in capsule form.

No violations of NRC requirements were identified during the NRC's last radiation safety and security inspections conducted on February 1-3, 2010, and the previous radiation safety inspection conducted on May 8, 2008.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspectors interviewed the Authorized User (AU), the Radiation Safety Officer (RSO), the referring physician, and other licensee personnel to determine the sequence of events that resulted in the reported medical event. In addition, the inspectors reviewed selected licensee records, licensee procedures, and the licensee's compliance with regulatory requirements for iodine-131 treatments.

2.2 Observations and Findings

A NMT reviewed a "Nuclear Medicine Service Request Form" for a patient that was signed and dated June 17, 2011, by the referring physician. The form stated that the reason for the nuclear medicine exam was thyroid cancer and it indicated that the patient should have, "radiopharmaceutical therapy, hyperthyroidism/thyroid carcinoma (I-131 Tx)." The NMT also noted the referring physician's, "Consultation Note" dated May 24, 2011. The Consultation Note stated a plan to administer 125 millicuries of iodine-131 if thyroid function is low, and 30 millicuries if thyroid function is high, followed by a probable higher dosage to follow later. However, the NMT did not read beyond where the Consultation Note stated "125 millicuries." The NMT highlighted the recommended 125 millicuries dosage, did not verify the dosage to be ordered with the AU, and ordered 125 millicuries of iodine-131 from a nuclear pharmacy on June 20, 2011. When the dosage was ordered, the Quality Management Program - Prescription Form (i.e., written directive) was not signed with the dosage amount by the attending physician (i.e., authorized user).

The inspectors noted that, on several other occasions as of June 30, 2011, including September 29, 2010, and April 13, 2011, licensee staff members ordered therapeutic iodine-131 from a nuclear pharmacy and the licensee's "Quality Management Program - Prescription Form" was not signed with the dosage amount by the attending physician. However, the Quality Management Program - Prescription Forms were signed with the dosage amount by the attending physician prior to dosage administration.

The patient who was to receive the iodine-131 dosage that was ordered on June 20, 2011, had a high thyroid function test result; therefore, the patient should have received 30 millicuries of iodine-131 with a probable higher dosage to follow later per the referring physician's recommendation.

On June 21, 2011, the 125 millicuries dosage of iodine-131 that was ordered on June 20, 2011, arrived at the licensee's facility. The referring physician usually observed iodine-131 dosage preparation and administration, and asked the NMT what the dose calibrator measurement was for dosages prior to administration. However, the referring physician did not observe preparation and administration of the dosage nor ask the NMT what the dose calibrator measurement was prior to dosage administration on June 21, 2011. Instead, the NMT and the AU prepared and administered the dosage.

The AU intended to administer the iodine-131 dosage recommended by the referring physician. The AU saw the Consultation Note with the NMT's highlight of the recommended 125 millicuries dosage and didn't notice that the Consultation Note stated a plan to administer 125 millicuries of iodine-131 if thyroid function is low, and 30 millicuries if thyroid function is high, followed by a probable higher dosage to follow later. Therefore, the AU and the NMT mistakenly believed that the referring physician recommended a dosage of 125 millicuries of iodine-131.

The licensee's practice was to have an AU and an NMT conduct dual verification that the radiopharmaceutical is correctly identified and that the dosage measures within ten percent of the desired dosage. The AU would then prescribe the observed measured dosage on the written directive prior to administration to the patient. Therefore, on June 21, 2011, the AU and the NMT conducted dual verification that the radiopharmaceutical was correctly identified and that the 115 millicuries dosage measured in the dose calibrator was within ten percent of the 125 millicuries dosage they thought was recommended by the referring physician. The AU then entered the prescribed 115 millicuries dosage on the written directive prior to it being administered to the patient. As a result, the administered dosage was as prescribed in the written directive; however, it was not prescribed by the referring physician.

On June 24, 2011, the patient returned for a scheduled whole body scan; however, the gamma camera was out of service. An NMT contacted the referring physician to inform him that the patient's whole body scan couldn't be completed. The referring physician asked the NMT what dosage was administered to the patient. After being told that the patient received 115 millicuries of iodine-131 instead of 30 millicuries, the referring physician informed the NMT that the patient did not receive the recommended dosage.

In response, the NMT informed the AU and the NMT who prepared and administered the dosage about the error. The AU determined that, since the administered dose differed from the referring physician's recommended dose by more than 50 rem to an organ and the administered dosage differed from the referring physician's recommended dosage by more than 20 percent, a medical event had occurred.

The inspectors determined that, since the administered dosage was in accordance with the dosage prescribed on the written directive, no medical event occurred. In addition,

the inspectors reviewed records of the other 14 iodine-131 administrations that occurred between August 26, 2009, and June 28, 2011, and no medical events were identified.

The AU and the referring physician determined that there would be no adverse consequences to the patient from the administration of 115 millicuries of iodine-131. They concluded that if the patient would have received the intended 30 millicuries dosage, the patient would have probably received about 125 millicuries of iodine-131 later to achieve the therapeutic objective.

The inspectors determined that the root cause of the unintended dosage being administered was the NMT and AU's failure to completely read the referring physician's, Consultation Note. The inspectors also identified contributing factors associated with the unintended dosage. The contributing factors were: (1) the NMT obtained the dosage to order from the referring physician rather than the AU; (2) the NMT ordered the dosage without verifying it with the AU; and (3) the referring physician was unavailable to observe the preparation and administration of the dosage.

2.3 Conclusions

An unintended dosage of iodine-131 was administered to a patient. The AU and the referring physician determined that there would be no adverse consequences to the patient from the unintended dosage. Since the unintended dosage was in accordance with the dosage prescribed on the written directive, no medical event occurred. No violations of NRC regulatory requirements were identified.

3 Notifications and Reports

3.1 Inspection Scope

The inspectors reviewed selected records and interviewed selected staff to understand the licensee's response to its discovery of the administration of the unintended dosage. The inspectors also reviewed the licensee's notification of a medical event to the NRC Operations Center dated June 24, 2011, and the licensee's retraction of the notification of a medical event to the NRC Operations Center on July 5, 2011. In addition, the inspectors reviewed the licensee's associated written report of the medical event dated June 28, 2011, and the licensee's amended report of the medical event dated July 26, 2011, to assess compliance with reporting requirements.

3.2 Observations and Findings

On June 24, 2011, the AU instructed the RSO to notify the NRC about the medical event. On June 24, 2011, the RSO notified the NRC Operations Center about the medical event. In addition, the referring physician informed the patient about the medical event on June 24, 2011. On July 5, 2011, the licensee's Associate RSO notified the NRC Operations Center to retract its June 24, 2011, notification of a medical event.

The licensee submitted its written report to the NRC regarding the medical event on June 28, 2011. The referring physician received the licensee's written report to the NRC

regarding the medical event prior to the onsite inspection conducted on July 1, 2011. The referring physician stated that the patient did not request a copy of the licensee's written report of the medical event.

3.3 Conclusions

No violations of NRC regulatory requirements were identified.

4 Licensee Corrective Actions

4.1 Inspection Scope

The inspectors reviewed the licensee's proposed corrective actions to prevent unintended dosages of iodine-131 from being administered to patients by interviewing selected staff. In addition, the inspectors reviewed the licensee's written report of the medical event dated June 28, 2011, and its amended report of the medical event dated July 26, 2011.

4.2 Observations and Findings

To prevent unintended dosages of iodine-131 from being administered to patients, the licensee immediately reviewed what occurred on June 24, 2011. The licensee's review included a meeting on June 27, 2011, to discuss the chronology of events, causes, corrective actions, and patient effects.

The licensee implemented actions to prevent unintended dosages of iodine-131 from being administered to patients. The licensee required that referring physicians may specify a recommended dosage on the "Nuclear Medicine Services Requisition Form" and, if a recommended dosage is absent from the form, the assigned NMT or AU may consult with the referring physician. The licensee also required NMTs to use only the completed Nuclear Medicine Services Requisition Form to determine the referring physician's recommended dosage. In addition, the licensee clarified that, although AUs may consult with the referring physician to determine whether or not they have a recommended dosage, the prescribed dosage in the written directive remains the full responsibility of the AU. The licensee also clarified that, whether or not a referring physician specifies a recommended dosage, only the AU will determine the prescribed dosage to be entered on the written directive. Lastly, the licensee required the AUs to review the written directive, including the specified dosage recorded by the NMT, and compare it against the Nuclear Medicine Services Requisition Form to verify consistency with the referring physician's recommended dosage.

4.3 Conclusions

The inspectors determined that the licensee planned and implemented corrective actions to prevent unintended dosages of iodine-131 from being administered to patients.

5 Exit Meeting

At the completion of the on-site inspection, the inspectors discussed the preliminary inspection findings in this report with licensee management during an exit meeting. The

licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature. A final telephonic exit meeting was conducted on August 4, 2011.

Partial List of Persons Contacted

+ Felicity Backfield, Associate Radiation Safety Officer
+ Julie Dawson, Ph.D., Radiation Safety Committee Member
+ Jeffrey Dossett, Administrative Director, Imaging
+ Kevin Ferguson, Health Physicist
^ Mark Haenchen, Radiation Safety Officer
Kyle Hurtgen, Nuclear Medicine Technologist
+ Paul Loewenstein, Radiation Safety Committee Chair
+ Michael Moxley, M.D., Radiation Safety Committee Member
+ Medhat Osman, M.D., Professor/Radiology
David Phegley, Nuclear Medicine Technologist
+ Hugh Robichaux, Nuclear Medicine Manager
Bruce Walz, M.D., Professor and Director, Radiation Oncology

+ Attended the on-site exit meeting July 1, 2011
^ Participated in the telephone exit meeting on August 4, 2011