ENCLOSURE 6 - INSPECTION RECORD

Region: III **Inspection Report No.** 2014001 **License No.** 24-32517-01
Docket No. 030-36583

Licensee: University of Kansas Cancer Centers
1000 East 101st Terrace
Kansas City, Missouri 64131

Locations Inspected: South facility: 1000 East 101st Terrace, Kansas City, Missouri
East facility: 4881 N.E. Goodview Circle, Lee's Summit, Missouri

Licensee Contact: Stephen Howard, Radiation Safety Officer **Telephone No**. 913-967-9056

Program Code: 02230 **Priority**: 2

Type of Inspection: ( ) Initial (X) Routine ( ) Announced
( ) Special (X) Unannounced

Last Inspection Date: 06/14/2012 **Date of This Inspection**: 05/19/2014 - 05/20/2014
With continued in-office review until 07/03/2014

Next Inspection Date: 07/03/2016 (X) Normal ( ) Reduced

Summary of Findings and Actions:

( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
(X) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector Andrew M. Bramnik, Health Physicist

/RA/ Date 07/23/2014
Signature

Approved Aaron T. McCraw, Chief, Materials Inspection Branch

/RA/ Date: 07/25/2014
Signature

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PART I - LICENSE, INSPECTION, INCIDENT/EVENT AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
23	05/22/2014	Added use for Tc-99m and In-111 for diagnostic imaging after NRC inspection finding
22	05/19/2014	Added authorized medical physicist
21	11/08/2013	Added possession and use for Ra-223
20	08/29/2013	Re-activated South facility for licensed use (excluding HDR) and added authorized medical physicist for HDR
19	06/17/2013	Added authorized user for HDR
18	10/31/2012	Added two authorized medical physicists
17	06/29/2012	Changed South facility to standby and only use for possession and storage of materials

The licensee submitted a license renewal application on July 1, 2014.

2. INSPECTION AND ENFORCEMENT HISTORY:

The last routine inspection of this licensee occurred between May 24 and 25, 2012, with continued in-office review until June 13, 2012. The inspector identified a Severity Level IV violation concerning the licensee's failure to notify the NRC within 60 days that they had not performed principal activities at the South facility for a period of 24 months, as required by 10 CFR 30.36(d)(4). The previous inspection on July 1, 2010, did not identify any violations.

3. INCIDENT/EVENT HISTORY:

No open items or events since the last routine inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The University of Kansas Cancer Centers operated a network of outpatient cancer treatment centers. The NRC License No. 15-32819-01 authorized the licensee to use specifically-identified byproduct materials for medical uses permitted by 10 CFR 35.200 (limited to flourine-18 (F-18) and carbon-11 (C-11)), 35.300 (limited to iodine-131 (I-131), yttrium-90, strontium-89, samarium-153, indium-111 (In-111), and radium-223 (Ra-223)), and 35.600 (for iridium-192 in an HDR). The license also authorized the possession of up to one curie of technetium-99m (Tc-99m) in any chemical and/or physical form for instrument calibration. The license authorized possession and use of byproduct material at the licensee's three clinics located in Kansas City (two clinics: North and South) and Lee's Summit, Missouri.

The Kansas City North and Lee's Summit facilities each employed two nuclear medicine technologists in their nuclear medicine departments. Both facilities conducted between four and six administrations of licensed material per day in the form of F-18 or C-11 unit doses for diagnostic Positron Emission Tomography (PET) scans. The Kansas City South facility employed one nuclear medicine technologist who conducted approximately ten administrations of licensed material per month in the form of Tc-99m unit doses for bone scans. The licensee received unit doses from area radiopharmacies with no bulk doses or generators.

The Kansas City North and Lee's Summit facilities each maintained at least one radiation oncologist on staff full time. Both locations utilized an HDR to treat approximately two patients per month. The licensee primarily used Contura and SAAVI applicators to treat breast cancer, and patients received treatments twice daily for five days. Both locations also administered unsealed material for therapeutic treatments. Although the licensee was authorized to use several isotopes for medical use under 10 CFR 35.300, they primarily used I-131 sodium iodide and Ra-223 radium dicholoride.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87131, 87132

Focus Areas Evaluated: All

The inspector toured the licensee's Kansas City South and Lee's Summit facilities to review and evaluate the licensee's use of byproduct material. The inspector identified that the licensee had been conducting diagnostic administrations of technetium-99m and indium-111 at the Kansas City South facility – activities that were not authorized on the NRC License. The South facility had been the subject of an NRC enforcement action in the past; on July 2, 2012, the NRC issued a Severity Level IV violation to the licensee concerning their failure to notify the NRC within 60 days that they had not performed principal activities at the South facility for a period of 24 months, as required by 10 CFR 30.36(d)(4). Between June 13, 2012, and August 29, 2013, the South facility had been listed on the license in standby-only status because the licensee intended to resume using byproduct materials at the facility in the future. In a letter to the NRC dated August 28, 2013, the Radiation Safety Officer (RSO) requested to re-activate the South facility. The RSO wrote that "This location was placed on a standby status in June 2012. We are in the process of installing a Siemens SPECT-CT scanner to replace the GE CT scanner that was originally there. We will need the ability to use and store radioactive materials in our hot lab in the operation of the scanner." The remainder of the licensee's letter and documentation focused on the technical evaluation of the SPECT-CT camera and a shielding analysis that had been performed on the facility walls. The licensee did not request to amend its authorized uses of byproduct material. On August 29, 2013, the NRC issued License Amendment No. 20 to the licensee, which re-activated the South facility for all of the authorized uses on the license except HDR. This item is discussed in greater detail in Section 4 below.

The inspector interviewed selected licensee staff members and reviewed records to evaluate the licensee's program for radiopharmaceuticals requiring a written directive. The licensee had not conducted any therapeutic modality other than Ra-223 radium dichloride "Xofigo" since the previous NRC inspection in 2011. While reviewing written directives, the inspector identified that the licensee failed to implement its written

procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee administered Ra-223 to a patient on two occasions and recorded the prescribed activity on the written directive in millicuries; however, the activity requested by the authorized user and physicist, and the activity administered to the patient, was in microcuries. Because the doses differed from the prescribed dose by more than 0.5 Sievert (50 rem) to an organ and the total dose delivered differed from the prescribed dose by 20 percent or more, both cases were reported as medical events. In both cases, the patient received the amount of Ra-223 intended by the physician, authorized user, and physicist. The licensee's failures to implement its procedure were isolated, did not demonstrate a programmatic weakness in implementation, and had no consequences to the patients. This item is discussed in greater detail in Section 4 below.

The inspector asked the licensee to not report the potential medical events to the NRC Headquarters Operations Center until the inspector could review the situation with his management. The inspector contacted the licensee by telephone on May 29, 2014, and informed them that the failure to accurately document the prescribed dose on the written directives met the criteria for a medical event as described above. The licensee reported the events to the Headquarters Operations Center on May 30, 2014, and submitted a written report to the Region III office dated June 9, 2014. The licensee's written report adequately addressed the elements required by 10 CFR 35.3045. Because the cause of the medical events were errors on the written directive and the patient received the dosage intended by the authorized user and physician, the prescribing physician elected to not inform the patient about the medical events.

Through interviews with the RSO and several licensee staff members, the inspector found that the licensee's staff was knowledgeable and conscientious of emergency and material handling procedures and techniques. The licensee successfully demonstrated routine equipment QA/QC checks, package receipt, area surveys, and waste handling and disposal procedures. A contract physicist performed quarterly audits to help oversee the nuclear medicine program. The inspector confirmed that these activities were routinely completed by reviewing selected records.

Licensed material was adequately secured and not readily accessible to members of the general public. The licensee possessed radiation survey meters that were calibrated and operational. Personal whole body and extremity dosimetry badges were observed being worn by the staff during the inspection, and records did not indicate doses in excess of 10 CFR Part 20 limits.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum 2403 survey meter with a model 44-38 energy-compensated GM detector, the inspector conducted independent surveys at each of the locations inspected. The inspector found no readings which would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

A. On May 19, 2014, while touring the hot lab at the South facility, the inspector identified a shielded container with a label for 25 millicuries (mCi) of Tc-99m. The nuclear medicine technologist told the inspector that the container held a unit dose for a bone scan that

had been administered earlier in the day. The RSO stated that the licensee conducted between one and three bone scans using unit doses of Tc-99m per week at the South facility. During the on-site inspection, the licensee identified that they had also utilized unit doses of indium-111 for diagnostic imaging studies.

Title 10 CFR 30.34(c) states, in part, that each person licensed by the Commission pursuant to the regulations in this part and parts 31 through 36 and 39 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license.

Conditions 6.F. through 8.F. of NRC License No. 24-32517-01 authorized the licensee to possess up to one curie of technetium-99m in any chemical and/or physical form. Condition 9.F. listed the authorized use for technetium-99m for instrument calibration.

Conditions 6.I. through 8.I. of NRC License No. 24-32517-01 authorized the licensee to possess up to 30 millicuries of indium-111 in indium chloride. Condition 9.F. listed the authorized use for indium-11 for any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300.

Contrary to the above, between September 24, 2013 and May 19, 2014, the licensee failed to confine the use of byproduct material to the purposes authorized in the license. Specifically, the licensee administered 92 unit doses of technetium-99m and 8 unit doses of indium-111 for diagnostic imaging studies at its facility in Kansas City, Missouri, and the licensee was not authorized to use either isotope for that purpose.

The root cause of the violation was the licensee's belief that they were authorized to administer technetium-99m and indium-111 under their NRC license because they had been authorized for these activities using the same SPECT-CT camera at a facility in Shawnee, Kansas. A contributing cause of the violation was the licensee's misunderstanding of their NRC license, which authorized the possession and use of each isotope but for different purposes than diagnostic studies. As corrective actions to restore compliance and to prevent recurrence, the licensee (1) cancelled scheduled administrations of technetium and indium until your license was amended to authorize those activities, (2) received an amended license that authorized those activities on May 22, 2014; and (3) submitted a license renewal application on July 1, 2014, requesting a simpler set of license authorizations.

B. While reviewing the licensee's records of administrations requiring a written directive on May 20, 2014, the inspector identified two examples of licensee's failure to implement its written procedures to provide high confidence that each administration is in accordance with the written directive, as required by 10 CFR 35.41(a). On April 1 and 29, 2014, the licensee administered Ra-223 to a patient in the form of radium dichloride "Xofigo." In both cases, the activity requested by the authorized user and the physicist was in microcuries; however, the licensee recorded the prescribed activity in millicuries. Because the doses differed from the prescribed dose by more than 0.5 Sievert (50 rem) to an organ and the total dose delivered differed from the prescribed dose by 20 percent or more, both cases were reported as medical events. In both cases, the patient received the amount of Ra-223 intended by the physician, authorized user, and physicist. The licensee's failures to implement its procedure were isolated, did not demonstrate a programmatic weakness in implementation, and had no consequences to the patients.

Title 10 CFR 35.41(a) states, in part, that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

The licensee developed and maintained its written procedure number DI-610, "Procedure for Safe Use of Unsealed Licensed Material" dated February 8, 2005, to provide high confidence that each administration is in accordance with the written directive. Section VII "Guidelines" of the licensee's written procedure requires personnel, in part, to "Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering. If the prescribed dosage requires a written directive, the patient's identity must be verified and the administration must be in accordance with the written directive."

Contrary to the above, on April 1 and 29, 2014, the licensee failed to implement its written procedure to provide high confidence that each administration is in accordance with the written directive. On the dates above, the licensee prepared written directives which called for 94.5 and 99.4 millicuries of radium-223 to be administered to patients, respectively. The licensee administered 98.3 and 101.4 microcuries of radium-223 to the patients. These administrations were not verified by licensee personnel to be in accordance with the written directives, as required by the licensee's written procedure.

The root cause of the violation was an oversight by the licensee's staff in completing written directives for administrations of radium-223 "Xofigo." On the dates above, the staff recorded prescribed doses on the written directive in units of millicuries when the intended (and administered) doses were in microcuries, resulting in medical events that were reported to the NRC. A contributing cause of the violation was the licensee's written directive form that had units for prescribed doses typed as millicuries. As corrective actions to prevent recurrence, on May 20, 2014, the licensee created a new written directive form for Xofigo administrations with units typed in microcuries.

5. PERSONNEL CONTACTED:

*# Stephen Howard, Radiation Safety Officer
*# Darrin Kistler, Director of Radiation Services
* Matt Pick, Manager of Nuclear Medicine Services
* Kenneth Guida, Authorized Medical Physicist
\# Habeeb Saleh, Chief Physicist
Amber Styles, Director of Compliance
Greg Sherich, Nuclear Medicine Technologist
DJ Reed, Nuclear Medicine Technologist
Additional nursing and administrative staff as available

* Attended preliminary on-site exit meeting on May 20, 2014
\# Attended final telephone exit meeting on July 3, 2014.

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