INSPECTION RECORD

Region: III **Inspection Report No.** 2017001 **License No.** 24-00889-01
Docket No. 030-02286

Licensee: Saint Luke's Hospital of Kansas City
4401 Wornall Road
Kansas City, MO 64111

Locations Inspected: Main hospital; Saint Luke's East Hospital, 100 N.E. Saint Luke's Boulevard, Lee's Summit, Missouri; and Medical Office Building, 20 N.E. Saint Luke's Boulevard, Lee's Summit, Missouri

Licensee Contact: Roy Sions, Radiation Safety Officer **Telephone No**. 314-577-5600

Program Code: 02110 **Priority**: 2

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

Last Inspection Date: 12/1-4/2015 **Date of This Inspection**: 10/30/2017-11/3/2017, with continued in-office review to 11/28/2017

Next Inspection Date: 10/30/2019 (X) Normal ( ) Reduced

Justification for reducing the routine inspection interval: N/A

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
(X) Followup on previous violations

Inspector: Deborah Piskura, Senior Health Physicist

/RA/ Date 12/05/2017
Signature

Approved: Aaron T. McCraw, Chief, MIB

/RA/ Date 12/07/2017
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT

No new licensing actions had been issued since the previous inspection.

At the time of the inspection, the Region III Materials Licensing Branch was reviewing an amendment request with several program changes of the licensee's activities including the removal of: (1) iodine-125 (I-125), cesium-137 (Cs-137), iridium-192 (Ir-192) sources for brachytherapy use; (2) three locations of use; and (3) the mobile nuclear medicine activities (ceased in Fall 2016).

2. INSPECTION AND ENFORCEMENT HISTORY:

The last routine inspection on December 1-4, 2015, resulted in two security-related violations. The inspector reviewed the licensee's corrective actions in response to these violations and determined that the licensee's actions were adequate; therefore, these violations were closed. Details of the inspector's review are included in the non-public Security Addendum to this Inspection Record. No violations of NRC requirements were identified during the previous inspection on August 19-22, 2013.

3. INCIDENT/EVENT HISTORY:

A review of ADAMS and NMED identified no open items. No events had been reported by the licensee since the last routine inspection.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

This licensee was a large medical institution and authorized to conduct licensed activities at 10 locations in the Kansas City area. The license was also authorized to provide mobile imaging services using a "scan-in-van" operation, however this activity ceased in 2016. The licensee operated a Type A broad scope program with authorization for materials in Title 10 of the *Code of Federal Regulations* (CFR) Sections 35.100, 35.200 (including positron emission tomography (PET) and strontium-82/rubidium-82 (Sr-82/Rb-82) generators for PET cardiac imaging), 35.300, 35.400, and 35.500, as well as iridium-192 in an high dose-rate remote afterloader (HDR) unit, yttrium-90 (Y-90) microspheres, and medical research and development protocols. The hospital employed a dedicated full-time Radiation Safety Officer (RSO) supported by an Assistant RSO. Collectively, the licensee's nuclear medicine departments were staffed with 15 nuclear medicine technologists (who rotate to the other sites) and PRNs who performed over 800 diagnostic nuclear medicine procedures monthly. Most locations performed a full spectrum of studies and received unit and bulk doses of technetium-99m (Tc-99m). The main hospital and its Lee Summit satellite hospital administered numerous I-131 dosages (capsules only) for whole body followup studies, hyperthyroid, and CA treatments. The department at the main hospital administered 8-10 Y-90 microspheres (SIR-Spheres®) treatments annually.

Radiation therapy activities were performed at the main hospital. The radiation oncology department was staffed with three authorized medical physicists (AMPs), three dosimetrists, and four authorized physician users. The licensee's administration of HDR patient treatments decreased since the previous inspection due to the departure of the primary prescribing physician; the last patient case was treated in July 2017. The HDR treatments were for breast and gynecological cancers. All HDR patient treatments were administered by the attending radiation oncologist and the AMP. Service, maintenance, and source exchanges were performed by the HDR device manufacturer. Brachytherapy activities involving low-dose implants were limited to I-125 eye plaques (5-6 cases/year). All other low-dose gynecological brachytherapy implants ceased in July 2016 with the departure of the primary prescribing authorized user. The licensee transferred its Cs-137 source inventory in 2016 to an authorized waste broker for disposal.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87134, "Medical Broad-Scope Programs"

Focus Areas Evaluated: All

This inspection consisted of interviews with licensee personnel, a review of select records, tours of the nuclear medicine and radiation oncology departments, and independent measurements. The inspector observed licensee personnel perform dose calibrator quality assurance tests, daily safety checks for the HDR unit and treatment room, inventory of sealed sources, security of byproduct material, and use of personnel monitoring. Several diagnostic administrations were observed during this inspection.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector performed direct radiation measurements in and around the licensee's nuclear medicine hot labs, imaging rooms, storage rooms, and the HDR unit and treatment room, which indicated similar results as noted in the licensee's survey records. Maximum levels were measured at the surface of the L-block within the main hot lab and on the surface of the HDR unit. Radiation levels in the unrestricted areas outside the hot labs, the imaging rooms, and the HDR treatment were indistinguishable from background. The inspector concluded that the radiation levels in the hospital complied with 10 CFR 20 limits. All survey measurements in the restricted areas were comparable to the licensee's survey results.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

The licensee used Sr-82/Rb-82 generators for cardiac PET imaging. The licensee performed approximately 250-300 PET studies per month. Users of this Sr-82/Rb-82 generator are unable to comply with certain NRC requirements in 10 CFR Part 35.

The licensee implemented all of the criteria in NRC Enforcement Guidance Memorandum (EGM) 13-003, "Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Dosages." The licensee developed written test procedures to ensure the infusion pump flow rate remained consistent and accurate, and that the radiation detector met the manufacturer's specifications. These tests were performed every 12 months and

records documenting the performance and the results of these tests were maintained (last tested July 16, 2015). All physician authorized users for 10 CFR 35.200 materials who were using Rb-82, the RSO, and the nuclear medicine technologists successfully completed training specific to the generator and infusion cart. The licensee maintained records of the activity of each dosage administered, as provided by the infusion cart.

Title 10 CFR 35.60 requires the licensee to calibrate instrumentation used to measure the activity of the dosage before it is administered to each patient. This calibration may either be performed in accordance with nationally recognized standards or calibration instructions provided by the manufacturer. However, the licensee was unable to calibrate a Sr-82/Rb-82 generator unit in accordance with the regulations because there are currently no nationally recognized standards or specific calibration procedures for calibrating detectors in a dynamic mode (i.e., while liquids are flowing past the detector). Until standards or procedures are developed, the licensee cannot comply with Section 35.60.

Title 10 CFR 35.63 requires the licensee to determine the activity of each dosage administered before medical use. Due to the 76-second half-life of Rb-82 and direct infusion of the Rb-82 from the dosage cart into the patient, users of this generator system are unable to measure a patient dosage of Rb-82 prior to administration.

Violations of 10 CFR 35.60 and 10 CFR 35.63 were identified during this inspection. In accordance with the NRC Enforcement Policy, these violations would normally be categorized at Severity Level IV. However, because the licensee met all of the criteria, in accordance with NRC EGM 13-003, the NRC is exercising enforcement discretion and not pursuing any enforcement action for these violations. These violations occurred because it is not possible for a user of a Sr-82/Rb-82 generator to use this device in accordance with the NRC regulations.

The inspector also identified security-related violations that are described in the non-public Security Addendum to this Inspection Record.

5. PERSONNEL CONTACTED:

Michel (Mitch) Bronson, Assistant Radiation Safety Officer
Derick Collins, Emergency Preparedness Coordinator
Albert Fung, Ph.D., Authorized Medical Physicist
Larry O'Brien, Security
#David Schemenauer, System Director-Safety & Emergency Preparedness
#Roy Sions, Radiation Safety Officer

Several members of the professional staff were also contacted during this inspection (nurses, nuclear medicine technologists, exercise physiologists, etc.).

Participated in final telephonic exit meeting on November 28, 2017.

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