

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

| <u>AMENDMENT #</u> | <u>DATE</u> | <u>SUBJECT</u> |
|--------------------|-------------|---|
| 09 | 01/29/2018 | Added authorization for Y-90 microspheres |
| 08 | 12/22/2015 | New RSO |
| 07 | 11/25/2015 | Licensee name change |

2. INSPECTION AND ENFORCEMENT HISTORY:

The NRC last performed routine inspections on August 24, 2011 and October 21, 2015. Violations of a security-related nature were identified during both inspections. Those identified during the 2011 inspection resulted in escalated enforcement action, therefore on March 21, 2012, the NRC conducted an enforcement follow-up inspection to verify the completion and effectiveness of the licensee's corrective actions. No additional violations were identified as a result of that inspection.

3. INCIDENT/EVENT HISTORY:

No open items or events since the last routine inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

SSM Health Cardinal Glennon Children's Hospital is a 195-bed inpatient and outpatient pediatric medical center in downtown St. Louis, Missouri, authorized by NRC Materials License No. 24-32264-01 to use radioactive material for diagnostic and therapeutic medical purposes, and for the irradiation of blood products. At the time of the inspection, one full-time technologist performed around half a dozen diagnostic administrations of radiopharmaceuticals per week at its nuclear medicine department using weight-based unit doses. Although authorized for therapeutic administrations of radiopharmaceuticals and yttrium-90 (Y-90) microspheres, the licensee had performed neither to date. The licensee continued to use a self-shielded irradiator on a daily basis for irradiating blood products.

The licensee maintained a Radiation Safety Committee (RSC), which met quarterly. The licensee also retained the services of an outside health physicist to perform quarterly audits of the nuclear medicine program. The licensee's RSO was based at the St. Clare Hospital in Fenton, Missouri,

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87131, 87132

Focus Areas Evaluated: All

The inspector toured the hospital to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector was unable to observe the conduct of licensed activities, as none were scheduled or ongoing at the time of the inspection. Instead, the inspector observed demonstrations of package receipt, instrument checks, dose preparation, waste handling, area surveys and spill response in the nuclear medicine department, and demonstrations of irradiator use in the blood bank. The inspector also discussed with licensee staff the implementation of procedures for Y-90 microsphere administrations, should one be performed in the future.

The inspector also reviewed a selection of records, including RSC meeting minutes, health physics audits, personnel dosimetry, protocols and checklists for Y-90 microspheres, as well as annual service reports and semiannual safety audits and leak test results for the irradiator.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum 2403 survey meter with a model 44-38 pancake probe and a Canberra UltraRadic energy-compensated GM meter, the inspector conducted independent surveys in the nuclear medicine department and blood bank. 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:

No violations of NRC safety requirements were identified as a result of this inspection. However, one Non-Cited Violation of NRC security requirements was identified, and is described in more detail in the non-publicly available Security Addendum to the letter issuing the report for this inspection.

5. PERSONNEL CONTACTED:

Kyle Hurtgen – Nuclear Medicine Technologist
Wallace Fuhrman – Radiation Safety Officer
Rick Hubbard – Director of Security
Kischa Jackson – Human Resources Leader
Danmei Zhang – Blood Bank Supervisor

Attended exit meeting on February 8, 2019.