INSPECTION RECORD

Region: III **Inspection Report No.** 2016001 **License No.** 24-02704-01
Docket No. 030-02310
EA-16-116

Licensee: Prime Healthcare Services – Kansas City, LLC d/b/a St. Joseph Medical Center
1000 Carondelet Drive
Kansas City, MO 64114

Locations Inspected: 1000 Carondelet Drive, Kansas City Missouri
930 Carondelet Drive, Kansas City, Missouri

Licensee Contact: Patrick M. O'Toole, M.D., RSO **Telephone No**. 913-708-4267

Program Code: 02240 **Priority**: 2

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

Last Inspection Date: 3/11/14 **Dates of This Inspection**: 4/26-27/16 with continued in-office review through 5/13/16.

Next Inspection Date: 4/26/2018 (X) Normal ( ) Reduced

Summary of Findings and Actions:

(X) 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
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector(s) Robert G. Gattone, Jr., Senior Health Physicist

/RA/ Date 5/17/2016
Signature

Approved Aaron T. McCraw, Chief, MIB

/RA/ Date 5/20/2016
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
69	5/15/15	Transfer of control and new licensee name
68	7/29/14	Changed authorized users
67	4/8/14	Changed locations of use

2. INSPECTION AND ENFORCEMENT HISTORY:

The last inspection was conducted 3/11/14 and no violations were identified. The previous inspection was conducted 5/21/12 and no violations were identified.

3. INCIDENT/EVENT HISTORY:

There were no incidents or events since the last inspection.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Nuclear medicine activities occurred Monday through Friday from 7:00 a.m. to between 2:00 p.m. and 7:00 p.m. Positron Emission Tomography (PET) was done on Tuesdays and Thursdays, and it was limited to use of a Bracco Cardiogen-82 generator for Rb-82 cardiac perfusion imaging.

The licensee conducted radioimmunoassays and administered iodine-131 (capsules only) for thyroid cancer treatment, hyperthyroidism treatment, and whole body scans to identify areas of metastatic thyroid cancer. Strontium-89 and Quadramet had not been administered since the last inspection. Nuclear medicine material was provided by a commercial radiopharmacy as unit dosages.

The licensee had not received its first shipment of yttrium-90 SIR-spheres®. The licensee was unsure when use of SIR-spheres® would be started.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: IP87131

Focus Areas Evaluated: 02.01, 02.02, 02.04, 02.05, 02.06, and 02.07

The inspector: (1) observed that licensed material was secured as required; (2) noted that the Radiation Safety Officer (RSO) was as authorized; (3) noted that the authorized users were as authorized; (4) observed a nuclear medicine technologist (NMT) conduct a survey instrument operation check, including a constancy check; (5) observed an NMT conduct package receipt surveys; (6) noted that the RSO stated that there were no major spills of licensed material, loss of licensed material, fires involving licensed material, floods involving licensed material, or medical events; (7) discussed the

licensee's commitments regarding use of yttrium-90 SIR-spheres® with the RSO; (8) discussed the importance of using the proper saline for the Cardiogen-82 generator with the RSO; (9) discussed the adverse consequences associated with using lactate ringer's solution instead of saline in the Cardiogen-82 generator with the RSO; (10) observed an NMT prepare a patient for a Rb-82 scan; (11) observed an NMT use a dose calibrator potentiometer setting of 504 for measuring Rb-82; (12) observed an NMT conduct a test done on the Cardiogen-82 generator before each day of use prior to the first Rb-82 patient administration that involved eluting Rb-82 into a vial and measuring it in the dose calibrator 3 minutes and 45 seconds after elution to verify that the eluate radioactivity determined by the Cardiogen-82 generator was within 10 percent of the back decay corrected radioactivity of the eluate that was measured in the dose calibrator; (13) observed an NMT prepare a technetium-99m radiopharmaceutical for a hepatobiliary scan, including measuring the unit dosage in a dose calibrator, using a syringe shield, wearing whole body and extremity dosimeters, wearing gloves, and using a syringe label; (14) observed an NMT administer a technetium-99m radiopharmaceutical intravenously including use of a towel pad to contain a potential spill, gloves, syringe shield, lead pig, and dosimeter badges; (15) observed an NMT prepare radioactive waste for disposal to the commercial radiopharmacy; (16) reviewed annual dosimeter badge results for 2014, 2015, and 2016 (through 3/19/16), and the highest whole body and extremity doses were 151 millirem and 1084 millirem, respectively; (17) reviewed selected records of administrations of iodine-131 with no issues noted; (18) observed written as low as is reasonably achievable (ALARA) patient instructions that were provided to iodine-131 patients; (19) obtained the license of the entity that calibrated the licensee's survey instruments to verify that the entity was authorized to do so; (20) reviewed annual ALARA audit records for 2014 and 2015, selected area survey records, and selected dose calibrator calibration records; (21) noted that the licensee had a pending license amendment request to release facilities to unrestricted use at the 930 Carondelet Drive location; (22) toured the 930 Carondelet Drive location facilities relative to the aforementioned pending license amendment request and did not see any licensed material; and (23) used an NRC-owned survey instrument to measure nothing above low background at the 930 Carondelet Drive facilities relative to the aforementioned pending license amendment request.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector used an NRC owned, calibrated survey instrument to measure: (1) 0.3 milliroentgen per hour (mR/hr) at selected surfaces of a waste storage room; and (2) 0.02 mR/hr at selected surfaces of the Cardiogen-82 generator and selected areas of the PET hot lab.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Regarding the licensee's use of a Bracco Cardiogen-82 Rb-82 (Rb-82) generator, Title 10 *of the Code of Federal Regulations* (CFR) 35.60 requires a licensee to calibrate the instrument used to measure the activity of the dosage administered to each patient or human research subject. This calibration may either be performed in accordance with nationally recognized standards or calibration instructions provided by the manufacturer. However, there are currently neither nationally recognized standards nor specific calibration procedures for calibrating the Cardiogen-82 detectors in a dynamic mode

(i.e., while liquids are flowing by the detector). Until such standards or procedures are developed, compliance with 10 CFR 35.60 is not possible.

In addition, 10 CFR 35.63 requires a 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 into the patient, users of the Cardiogen-82 generator system are unable to measure patient dosages of Rb-82 prior to administration.

On several occasions as of April 26, 2016, including April 26, 2016, the licensee used a Bracco Cardiogen-82 Rb-82 generator for cardiac imaging and could not comply with 10 CFR 35.60 (the medical use calibration requirements for the radiation detectors associated with Rb-82 generator systems) and 10 CFR 35.63 (the inability of users of those systems to determine the dosage of the Rb-82 before medical use).

The licensee used documentation of the infusion cart maintenance performed by the manufacturer to document the completion and results of the infusion rate and radiation detector test. The only authorized user (AU) for medical uses under 10 CFR 35.200 who used Rb-82 chloride was also the licensee's Radiation Safety Officer, and he successfully completed the manufacturer's training specific to the manufacturer and model of generator and infusion cart that was used, which included: (1) elution and quality control procedures needed to determine Rb-82 activity and the Sr-82 and Sr-85 breakthrough levels; (2) dose calibrator calibration procedures; and (3) safety procedures for the clinical use of Rb-82 chloride. The licensee's quality control procedures for calibrating the radiation detector in the infusion cart included: (1) performance of the Rb-82 activity constancy check comparison with Rb-82 measured in a calibrated dose calibrator; (2) how to adjust the infusion cart readout setting; and (3) when these tests are required by the manufacturer. The licensee maintained documentation that all AUs using Rb-82 and the RSO have satisfactorily completed such training. The licensee also recorded the activity of each dosage administered, as provided by the infusion cart.

Although violations of 10 CFR 35.60 and 35.63 were identified, the licensee met all of the criteria in EGM 13-003, (available at www.nrc.gov) for use of enforcement discretion; therefore, the NRC is exercising enforcement discretion and will not issue any enforcement action for these violations.

5. PERSONNEL CONTACTED:

Amy Alexander, Director of Radiology
Brian Biak, Bracco Representative
Brett Johnson, NMT
Nick Kromnacker, R.N.
Patrick O'Toole, M.D., RSO
Donna Stanton, NMT
Jeff Voss, Bracco Clinical Application Specialist
Marcia West, NMT

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