INSPECTION RECORD

Region III Inspection Report No. 2013-001 **License No.** 24-18625-01
Docket No. 030-13959

Licensee: Midwest Division – RMC, LLC
d/b/a Research Medical Center
2316 East Meyer Blvd.
Kansas City, MO 64132

Locations (Authorized Site) Being Inspected: 2316 East Meyer Blvd.
Kansas City, MO 64132

6420 Prospect Avenue
Kansas City, Missouri (the Tower)

Licensee Contact: Stephen T. Slack, Ph.D, RSO **Telephone No**. 816-276-4449

Priority: 2 **Program Code:** 02240

Date of Last Inspection: October 7, 2014 **Date of This Inspection:** July 25-26, 2013

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

Next Inspection Date: July 2015 (X) Normal ( ) Reduced
Justification for reducing the routine inspection interval: N/A

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
( ) Followup on previous violations

Inspector: ***/RA/ by Aaron T. McCraw for*** Date: ***08/21/13***
Geoffrey M. Warren, Health Physicist

Approved: ***/RA/*** Date: ***08/21/13***
Aaron T. McCraw, Chief, MIB

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

1. AMENDMENTS AND PROGRAM CHANGES:

AMENDMENT #	DATE	SUBJECT
54	Nov. 2011	Add new cardiac stress lab, release previous lab
55	Feb. 2012	Revise HDR and microspheres procedures; remove authorized users (AUs) from license
56	May 2012	Delete material from license; add AU
57	Nov. 2012	Update HDR information, delete material from license
58	June 2013	Add model number for palladium-103 seeds

2. INSPECTION AND ENFORCEMENT HISTORY:

No violations were cited as a result of inspections performed in October 2009 and October 2011.

3. INCIDENT/EVENT HISTORY:

None.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The licensee was a 390-bed hospital located in Kansas City, Missouri, with authorization to use byproduct materials in Sections 35.100, 35.200, 35.300, and 35.400, as well as iridium-192 in a high dose rate remote afterloader (HDR) unit and yttrium-90 for microspheres treatments. Licensed activities were conducted only at the facilities identified on the license. The hospital operated a gamma stereotactic radiosurgery device under a separate license.

The nuclear medicine department operated two nuclear medicine areas under the license – main nuclear medicine at the hospital and an outpatient cardiology clinic at 6420 Prospect Avenue. The two areas were staffed with four full-time nuclear medicine technologists who rotated between the two areas and two nurses who assisted as needed. The licensee's nuclear medicine staff typically administered 450 diagnostic doses monthly, 30 iodine-131 therapy doses annually, occasional therapy procedures using samarium-153, and 25 microspheres treatments annually. Diagnostic procedures included a variety of imaging and uptake procedures using technetium-99m and other isotopes received as unit doses from a licensed radiopharmacy. Iodine-131 doses were received as capsules. Microsphere doses were prepared from bulk microspheres. All waste was either held for decay-in-storage or returned to the radiopharmacy. The hospital had a nuclear medicine technologist training program.

The outpatient cardiology clinic had been added as a location of use since the previous inspection. The location and layout of the facility were consistent with information provided to the NRC as part of the amendment request to add the site.

The radiation oncology department was staffed with three physician authorized users, three medical physicists, and two dosimetrists. Two therapists assisted during HDR procedures. The radiation therapy staff treated approximately 30 HDR patients annually, generally performing 2 to 5 fractions per patient, and 75 prostate implant brachytherapy patients annually using iodine-125 or palladium-103 seeds.

2. SCOPE OF INSPECTION:

Inspection Procedures Used: 87131, 87132

Focus Areas Evaluated: 03.01 – 03.08, 03.01 – 03.08

The inspector observed two diagnostic administrations, including dose preparation and disposal; monitoring of an in-house iodine-131 therapy patient; package receipt survey and wipe; and daily checks of the HDR unit. Licensee personnel demonstrated morning checks in nuclear medicine, setup for HDR treatments, and daily contamination surveys, and described a variety of diagnostic and therapeutic nuclear medicine procedures, HDR treatments, prostate implant procedures, and room setup and clearance surveys for iodine-131 patient rooms. The inspector noted no concerns with these activities except as noted below in Section 4.A.

The inspector reviewed written directives for radiopharmaceutical therapies, HDR treatments, prostate implant procedures, and identified no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry records indicated no exposures of regulatory concern. Radiation Safety Committee minutes indicated that the committee met routinely, had appropriate membership, and discussed appropriate topics and concerns.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector performed independent and confirmatory radiation measurements using a Ludlum 2403 survey instrument calibrated in April 2013, which indicated results consistent with licensee survey records and postings. Surveys were performed in nuclear medicine and radiation oncology areas and in public areas surrounding these departments. In addition, the inspector surveyed the nuclear medicine waste storage area and the radiation oncology hot lab, which the licensee has requested be released for unrestricted use.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

A. During review of prostate implant brachytherapy records, the inspector noted that the authorized user had completed the post-treatment plans for only three of thirty-five implant procedures performed since February 4, 2013. The authorized user had not contoured the post-implant scans, so the physicist was unable to complete the plans. The physicist had not brought this concern to department management or to the radiation safety officer. The licensee's written procedure did not specify a time frame for completion of the plans.

The authorized user completed the contours for all but the most recent few scans, which are still in process, prior to completion of the onsite inspection. The

physicist completed the post-treatment plans the following week. No medical events were identified through the licensee's review of the post-treatment plans; the inspector confirmed this through a review of selected plans.

No violation was identified because no medical events occurred during the period of concern, and the licensee's written procedure included all topics required under Title 10 of the *Code of Federal Regulations* (CFR) 35.41. However, the lack of timely review of the implants could have prevented the licensee from identifying any medical events, evaluating them, and taking action to prevent recurrence.

The licensee has committed to certain actions to prevent the situation from recurring. These actions include: (1) the dosimetrist notifying hospital management if the post-treatment plan has not been completed within 30 days after an implant and once the plan is completed, (2) the Medical Staff Office providing penalties to the authorized user for continued failure to complete required medical records, and (3) the Chief of Clinical Operations of Radiation Oncology compiling a written report of completion of seed implant cases each month for review by the Radiation Safety Committee.

B. In January 2013, the licensee reported to the NRC Operations Center, a possible medical event in which an unintended patient was given a diagnostic dose of technetium-99m.

A nurse sent a vague order to nuclear medicine for a cardiac stress test for the patient, and the procedure was performed. In reviewing the case, nuclear medicine staff noted that the order did not specify a nuclear medicine stress test. The physician had intended a non-nuclear stress test, but the nurse had not realized the difference. The licensee determined that the administration did not meet the definition of a medical event because the dose did not exceed 5 rem whole body or 50 rem to any organ. Based on this, the licensee retracted the report. The licensee trained the nurse and similar staff about the different types of cardiac stress tests, and nuclear medicine staff were reminded to challenge vague orders. The inspector did not identify any violation concerning the administration.

5. PERSONNEL CONTACTED:

James Bower, M.D., Chief Medical Officer
Robert Gilliam, Medical Physicist
Michael Scott, Administrative Imaging Director
John Sheldon, M.D, Radiation Oncology (by phone)
*# Stephen T. Slack, Ph.D., Radiation Safety Officer
Matt Sogard, Chief Operating Officer
Aric Stallman, Assistant Director, Imaging
and other staff from nuclear medicine and radiation oncology

Individuals present at preliminary onsite exit meeting on July 26, 2013
* Individual present at telephonic exit meeting on August 7, 2013