NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Midwest Division - RMC, LLC d/b/a Research Medical Center 2316 East Meyer Blvd. Kansas City, MO 64132 REPORT NUMBER(S) 2017001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-13959	24-18625-01	August 8 - 30, 2017

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

[X] 1. Based on the inspection findings, no violations were identified.

[ ] 2. Previous violation(s) closed.

[ ] 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(s):

[ ] 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Kevin G. Null	Kevin G. Null	9/1/17
BRANCH CHIEF	Aaron T. McCraw		9/12/17

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131 and 87132	03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2240	2	Ruth Schukman-Dakotas, RSO	(816) 276-3692

☑ Main Office Inspection Next Inspection Date: 08/30/2019

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine, unannounced inspection of a 600-bed medical center that was authorized for byproduct material described in 10 CFR Sections 35.100, 200, 300, 400, 600, and yttrium-90 permitted in Section 35.1000. The nuclear medicine department was staffed by 4 certified nuclear medicine technologists (CNMT's) who performed an average of 15 - 20 diagnostic studies per day. The department had five imaging rooms and one hot lab. Unit doses and iodine-131 capsules for 35.300 radiopharmaceutical therapy procedures were provided by a local, licensed radiopharmacy. PET studies were performed twice each week by a contract service, DMS Health, out of South Dakota. The licensee performed an average of two radium-223 dichloride Xofigo, four iodine-131 thyroid cancer, three iodine-131 hyperthyroid, and two yttrium-90 treatments each month. The licensee also conducted about 30 HDR treatments, and 30 iodine-125 prostate implants per year. The licensee recently had a change in the RSO, but had not yet received their amended license. The inspector contacted Region III licensing staff who confirmed that the amendment request was approved and had been mailed to the licensee.

PERFORMANCE OBSERVATIONS

The inspector toured the nuclear medicine department, observed CNMTs conduct licensed activities, interviewed occupational and non-occupational workers, and reviewed records pertaining to compliance with NRC regulations, the licensee's radiation protection program, and NRC license. The inspector observed a CNMT check in a shipment of unit doses received from the radiopharmacy. The CNMT, who was wearing a laboratory coat, gloves and proper dosimetry, performed appropriate radiation level surveys and smears for contamination. The inspector also observed a CNMT prepare a unit dose for a patient injection, measure the dose in a calibrated does calibrator, and place the dose in a lead syringe shield. This was preformed while wearing a laboratory coat, gloves, and proper dosimetry. The inspector observed another CNMT use a portable, calibrated survey instrument while demonstrating how end of day surveys were conducted in restricted areas.

(continued on Part 2)

NRC FORM 591M PART 2
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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(Continued)

The inspector reviewed a selection of written directives for iodine-131, yttiyum-90 microsphere, radium-223 Xofigo, and HDR treatments. The inspector also reviewed records documenting results of annual audits, radioactive waste disposal, area surveys, and dosimetry records. For calendar year 2106, the maximum whole body exposure was 480 millirems and extremity was 4,820 millirems. The inspector observed an HDR treatment, which was performed by an approved authorized user (AU). The treatment was the second of five fractions. The signed written directive dated August 3, 2017, was for 3,000 centigray (cGy) total, 600 cGy per fraction. In addition to the AU, an authorized medical physicist was present during the treatment.

During the review of records pertaining to radiopharmaceutical therapy treatments, the inspector noted that the licensee had recently released a patient who had received 157 millicuries of iodine-131. Records of two separate surveys of the dedicated treatment room after the patient had been released indicated the presence of removable contamination. The inspector was escorted to the room and noted that the room was posted, but not locked. After the onsite portion of the inspection, the inspector obtained and reviewed the results of the smears and determined that the aggregate quantity of activity in the room was below the level categorized for a cited violation against 10 CFR Section 1802 in accordance with the current NRC enforcement policy.

The inspector requested that the licensee evaluate the potential for unauthorized access to the room and spread of contamination. An evaluation was conducted by the licensee after the onsite portion of the inspection. In a letter dated August 28, 2017 (ML17242A142), the licensee provided its assessment which included interviews of nursing staff, a review of security camera footage, and smears for contamination in unrestricted areas outside the patient room. There was no indication of unauthorized access to the room, nor was there any evidence of the spread of contamination. No violations were identified regarding this issue, however, as a result of discussions with licensee management over concerns about removable contamination identified in the room, the potential for unauthorized access and spread of contamination, and the lack of security of the room, the licensee installed a keyed lock on the door to the room before the end of the day of the onsite inspection on August 8, 2017.

No violations of NRC requirements were identified. A final exit was conducted on August 30, 2017, following the inspector's receipt and review of the licensee's August 28, 2017 letter.