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
Mercy Hospital South 10010 Kennerly Road St. Louis, MO 63128 REPORT NUMBER(S) 2019001	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
030-10108	24-01041-04	May 20-21, 2019

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:

☒ 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	Dennis P. O'Dowd	Dennis P. O'Dowd	05/21/19
BRANCH CHIEF	Aaron T. McCraw		6/14/19

NRC FORM 591M PART 3
(07-2012)
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Docket File Information

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

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	2	James Monroe, Ph.D., RSO	(314) 525-4064

☑ Main Office Inspection Next Inspection Date: 05/20/2021

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine, unannounced inspection of a 767-bed regional hospital authorized to use licensed materials under 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000. The licensee had three locations of use at its main campus in St. Louis, Missouri, and at one off-site location in southwestern St. Louis. The licensee employed three full-time nuclear medicine technologists (NMTs) at the main hospital nuclear medicine department; one full-time and two part-time NMTs, and two PRNs, at the Mercy Heart and Vascular Testing cardiac clinic; and one full-time and one part-time NMT, and one PRN, at the PET/CT clinic, which is located at the main campus. At the time of the inspection, the licensee had temporarily discontinued its use of licensed material at its Watson Road cardiac clinic pending the hiring of additional staff. The licensee performed approximately 500+ diagnostic nuclear medicine procedures monthly, primarily cardiac stress tests, lung scans using Xe-133, HIDA, gastric emptying, bone scans, gall bladder, renal, and PET imaging using F -18. The licensee received unit doses, bulk Tc-99m, and I-131 in capsule form from a licensed radiopharmacy. The licensee consultant physicist conducted the radiation safety program audits on a quarterly basis. The cancer center located at the main hospital was staffed with two oncologists, two authorized medical physicists (AMP), (with another AMP backup), and two dosimetrists. The licensee conducted approximately twenty high dose-rate brachytherapy (HDR) gynecological cancer treatments per year. The HDR sources were exchanged quarterly. The licensee also performed approximately five Y-90 SIR-sphere treatments annually. Manual brachytherapy procedures using I-125 prostate seed implants were last conducted on July 13, 2017, and there were currently no plans to resume this program. The licensee performed approximately 30 iodine-131 (1-131) hyperthyroid and cancer therapy treatments annually, and performed approximately twelve Ra-223 Xofigo treatments per year. As was noted during the previous inspection, the licensee is actively building a new cancer center facility on the main campus with completion expected sometime in 2020, with the plan is to move HDR, PET/CT, and the radiation oncology department to the new facility. The licensee intends to submit an amendment request to NRC in the near future with its proposed new facility.

PERFORMANCE OBSERVATIONS

The inspection consisted of interviews with select licensee personnel; tours of materials use and storage facilities, including the main nuclear medicine department, the heart center, the PET/CT clinic, and the oncology department;

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PROGRAM SCOPE

(cont'd. from previous page)

a review of select records; and independent measurements by the inspector. The inspector observed several administrations of Tc-99m doses, as well as one F-18 PET dose, to patients for various studies, with no issues noted. In each area of use, licensee staff discussed/demonstrated dose calibrator daily constancy checks, package receipt and check-in procedure, and daily and weekly contamination surveys and wipes, proper handling of radioactive waste and disposal procedures, with no issues identified. Interviews of staff indicated an adequate knowledge of radiation safety and emergency response procedures. No therapeutic procedures were conducted by the licensee at the time of the inspection. The inspector had the RSO/AMP discuss/demonstrate the HDR unit's: (1) security of licensed material; (2) daily spot checks; (3) emergency equipment and procedures; (4) safety procedures and instructions; (5) door interlock system; and (6) radiation monitoring equipment. The RSO/AMP also discussed/demonstrate the implementation of procedures for Y-90 microspheres as well as the preparation and administration of microsphere injections. The inspector conducted a comprehensive review of the HDR, manual brachytherapy, I-131 and Ra-223 cancer therapy, and Y-90 microspheres written directives and treatment plans, with no issues noted.

The inspector reviewed a selection of written records, including radiation safety committee minutes, quarterly program audits conducted by an outside consultant, package receipts, waste disposal records, annual refresher training, DOT Hazmat training, linearity and accuracy of the dose calibrator, daily area surveys and weekly wipe tests, sealed source leak tests, and dosimetry records. The review of dosimetry records indicated no exposures of regulatory concern. The inspector conducted an independent and confirmatory surveys and found no residual contamination or exposures to members of the public in excess of regulatory limits.

No violations of NRC requirements were identified as a result of this inspection.