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
St. Luke's Hospital 232 S. Woods Mill Rd. Chesterfield, MO REPORT NUMBER(S) 2018-001	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
030-02305	24-01570-03	7/26-27/18

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	Robert G. Gattone, Jr.	Robert G. Gattone, Jr.	8/7/18
BRANCH CHIEF	Geoffrey Warren		8/8/18

NRC FORM 591M PART 3
(07-2012)
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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131 & 87132	87131: 02.01-02.07 & 87132: 02.01-02.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Christopher Durbin, RSO	(314) 205-6218

☑ Main Office Inspection Next Inspection Date: 07/26/2020

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a an unannounced, routine inspection of a medical licensee with facilities in Chesterfield and O'Fallon, Missouri. The licensee was authorized for medical uses as per 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, and 35.600. In addition, the licensee was authorized for 35.1000 medical use involving a NeoVista Epi-Rad 90 ophthalmic applicator device; however, the device was never used, and it was transferred to the manufacturer. The nuclear medicine department was staffed with 4 full-time nuclear medicine technologists (NMT), who performed approximately 200 of the full spectrum of diagnostic procedures monthly, as well as approximately 4 Ra-223 Xofigo treatments per month. The main hospital also performed approximately 50 I-131 hyperthyroid and cancer therapies annually. The nuclear medicine department at O'Fallon was staffed with 1 part-time NMT, who performed approximately 70 cardiac stress tests per month. The work hours at this facility were Tuesday- Thursday, 7:30AM-3:30PM. The nuclear medicine department at 121 St. Luke's Center Drive was staffed with 2 full-time and 2 part-time NMTs, who performed approximately 200 diagnostic nuclear medicine procedures, mostly cardiac stress tests, bone scans, and I-131 whole body scans. The licensee received unit doses, bulk Tc-99m, and I-131 in capsule form from a licensed radiopharmacy. The cancer center located at the main hospital was staffed with one oncologist, one authorized medical physicist (AMP), and two dosimetrists. The licensee conducted approximately 10 high dose-rate brachytherapy (HDR) treaments annually, primarily for gynecological and breast cancers. The licensee also performed approximately 16 manual brachytherapy treatments using I-125 for eye melanoma annually. The licensee also possesses 10 Cs-137 sealed sources, which are in long-term storage and no longer used for patient treatments.

Performance Observations

The inspector: (1) observed that the Radiation Oncology Department was locked when unattended resulting in security of licensed material; (2) observed that the nuclear medicine hot lab was secured as required; (3) observed an NMT demonstrate how she conducted a daily constancy check for a calibrated survey instrument prior to use; (4) observed that a high dose rate remote afterloader device (HDR) was as required and the HDR ion chamber was calibrated by an authorized person; (5) observed applicable staff wearing their dosimeter badges; (6) verified that the licensee's Oncentra software was Version 4.5.3; therefore, there were no concerns pertinent to Elekta's Field Corrective Action Reference FCA-NU-0004 document, dated August 2017; (7) observed that the RSO was as required; (8) reviewed selected records

GW 8/9/18

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PROGRAM SCOPE

of HDR treatments, including written directives, treatment plans, anatomical images overlayed with dosimetry information, pre- and post-treatment printouts showing the treatment parameters for the HDR to execute operations to achieve the objective of the written directive and the treatment plan; (9) observed that the aforementioned stored Cs-137 sources were secured as required; (10) noted that the licensee conducted quarterly inventories of sealed sources, including the Cs-137 sources; (11) noted that the licensee did not identify any medical events since the last inspection; (12) noted that there was no loss, theft, fire, flood, overexposures, major spills, or radioactive material device safety failures since the last inspection; (13) observed an HDR breast treatment including the licensee's use of the treatment planning software to generate the treatment plan, spot checks prior to treatment, source activity verification, interlock checks, radiation monitor checks, timer accuracy checks, closed circuit television checks, intercom checks, source position indicator checks, and emergency equipment checks; (14) observed the licensee use independent software to verify that the treatment plan is correct; (15) noted that the licensee verified the patient's identity by 2 means; (16) observed that the authorized user (AU) approved the treatment plan prior to treatment; (17) observed the authorized medical physicist (AMP) verify that the HDR device was programmed to execute the treatment as per the treatment plan and the written directive prior to treatment; (18) observed the AMP verify that the HDR device was programmed to execute the treatment as per the treatment plan and the written directive after the treatment; (19) observed that the licensee's HDR emergency procedure was posted at the HDR console; (20) noted that the licensee conducted post HDR treatment ambient exposure rate measurements of the patients; (21) used an NRC-owned, calibrated survey instrument to conduct an independent survey of selected surfaces of the HDR vault during a treatment and the result was 0.01mR/hr; (22) observed that the AU and the AMP manned the HDR console during HDR treatments; (23) noted that the annual, highest whole body and extremity doses for 2016 through June 2018 were 145 mrem and 480 mrem, respectively; (24) reviewed selected records showing that Xofigo, I-131, and I-125 eye plaque treatments were administered in accordance with the applicable written directives/treatment plans; and (25) reviewed records showing that patients were released as required.

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

CW
8/8/18