

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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| <p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Mercy Hospital - St. Louis</p> <p>615 South New Ballas Road St. Louis, MO 63141</p> <p>REPORT NUMBER(S) 17001</p> | <p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p> | |
| <p>3. DOCKET NUMBER(S)</p> <p>030-02283</p> | <p>4. LICENSE NUMBER(S)</p> <p>24-00794-03</p> | <p>5. DATE(S) OF INSPECTION</p> <p>July 25-27, 2017 w/ in-office review through August 7, 2017</p> |

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 violation(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 | Zahid Sulaiman, Health Physicist | <i>Zahid Sulaiman</i> | 8/18/2017 |
| BRANCH CHIEF | Aaron T. McCraw, Chief, MIB | <i>A. McCraw</i> | 8/18/17 |

Docket File Information

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

SUPPLEMENTAL INSPECTION INFORMATION

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|---------------------------------|----------------------|--|---|
| 1. PROGRAM CODE(S) 02240 | 2. PRIORITY 2 | 3. LICENSEE CONTACT Robert Turco, Ph.D, RSO | 4. TELEPHONE NUMBER (314) 251-6844 |
|---------------------------------|----------------------|--|---|

- Main Office Inspection Next Inspection Date: 07/25/2019
- Field Office Inspection Mercy Clayton & Clarkson, 15945 Clayton Rd,
- Temporary Job Site Inspection David C. Pratt Cancer Center, 607 S. New Ballas Rd,

PROGRAM SCOPE

This was a routine inspection of a 900-bed 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 12 off-site locations around St. Louis. The licensee employed four full-time nuclear medicine technologists (NMTs) at the main hospital nuclear medicine department; three full-time NMTs at the heart hospital; and two full-time NMTs at the main hospital PET/CT clinic. The licensee performed approximately 800+ diagnostic nuclear medicine procedures monthly, roughly the full spectrum of diagnostic tests. The licensee elutes a molybdenum-99 (Mo-99) generator at least three times a day to prepare technetium-99m (Tc-99m) doses. The licensee receives a Mo-99 generator every Sunday morning. The licensee also received unit doses, bulk Tc-99m, and iodine-131 (I-131) both in capsule and solution form from a licensed radiopharmacy. The licensee possessed cesium-137 (Cs-137) seeds, a strontium-90 eye applicator and a Cs-137 calibration source, these sources has not been used for several years and are stored at the long term storage facility.

The main hospital blood bank possessed the blood irradiator which was used daily by the blood bank staff. The cancer center located at the main hospital was staffed with six oncologists, four authorized medical physicists (AMP), and five dosimetrists. The licensee performed approximately 200 I-131 hyperthyroid and cancer therapy treatments annually. The licensee conducted approximately 70 high dose-rate (HDR) remote afterloader procedures mostly gynecological and some breast cancer treatments annually. The HDR sources were exchanged quarterly, with the most recent source exchanged on May 10, 2017. The licensee also performed approximately five yttrium-90 (Y-90) SIR-spheres microspheres treatments and three manual brachytherapy procedures using iodine-125 or palladium-103 for prostate seed implants annually.

The Mercy Clayton and Clarkson hospital nuclear medicine department was staffed with a full-time NMT who performed approximately 70 diagnostic procedures monthly. The oncology department was staffed with one oncologist and an AMP supported from the main hospital who performed approximately 10 HDR procedures annually, mostly mammosite and breast cancer treatments.

The licensee radiation safety department conducted the radiation safety program audits on a quarterly basis.

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(Continued)

The licensee also performed radium-223 (Ra-223) Xofigo therapy procedures at the main hospital. The licensee was planning to take over the RSO and the AMP responsibilities for the Mercy Hospital Jefferson (License No. 24-18315-01) location this year. The Mercy Hospital Jefferson will submit the license amendment request for the transition of RSO and AMP duties.

PERFORMANCE OBSERVATIONS

The inspection consisted of interviews with select licensee personnel; review of select records; and tours of the nuclear medicine, PET/CT clinic, cancer center, long-term sealed source storage facility, heart hospital, and Mercy Clayton and Clarkson hospital. The inspector observed the administration of Tc-99m doses to a patient for cardiac stress test, one therapeutic administration of I-131, HDR treatment plan verification, two HDR vaginal cylinder procedures, the preparation for a Ra-223 Xofigo administration, a Y-90 SIR-spheres microspheres treatment procedure and the package receipt surveys and wipes procedure.

The inspector: (1) observed the NMT and health physic technician conduct a physical inventory of sealed sources, and all sources were accounted for; (2) had the NMT demonstrate Mo-99 generator elution and checks, kit preparation, QC, kit labeling and tracking; (3) had the NMT demonstrate the dose calibrator constancy check, the end of the day daily area surveys and weekly wipe tests, and proper handling of radioactive waste and disposal procedures. The inspector had the AMP 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 inspector had the AU and NMT demonstrate implementation of procedures for Y-90 SIR-spheres microspheres as well as the preparation and administration of microsphere injections. The inspector reviewed ten HDR (gynecological and breast cancer), three manual brachytherapy prostate seeds implant, four I-131 cancer therapy, and five Y-90 SIR-spheres microspheres written directives and treatment plans.

The inspector reviewed the following records: radiation safety committee minutes, quarterly program audits, package receipts, waste disposal records, DOT Hazmat training, linearity and accuracy of the dose calibrator, daily area surveys and weekly wipe tests, and sealed source leak tests. The inspector reviewed the dosimetry records for 2016, and through June 30, 2017 indicating the maximum annual dose to be 733 mrem - DDE; and 10,678 mrem - SDE. 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.

The inspector identified a minor violation of 10 CFR 35.2092 at Mercy Clayton and Clarkson hospital. The licensee failed to document the survey results of a decay-in-storage waste container before disposing of it as biohazard waste. Based on waste container decay times and discussion with the NMT, no radioactive materials was inappropriately disposed of, the minor violation was of a paperwork related nature. The licensee implemented immediate corrective action and committed to document the survey results. This failure constitutes a violation of minor significance and is not subject to formal enforcement action.

The inspector closed the three SL IV security violations from the previous inspection (IR No. 03002283/2015001). The inspector verified and confirmed that the licensee's corrective actions were implemented/completed by interviewing select staff, reviewing relevant records and documents.