

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: St. Anthony's Medical Center 10010 Kennerly Road St. Louis, MO 63128 REPORT NUMBER(S) 17001	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-10108	4. LICENSE NUMBER(S) 24-01041-04	5. DATE(S) OF INSPECTION April 19, 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:

- 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>	4/19/17
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB	<i>ATM</i>	5/19/17

Docket File Information

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3. DOCKET NUMBER(S) 030-10108	4. LICENSE NUMBER(S) 24-01041-04	5. DATE(S) OF INSPECTION April 19, 2017
6. INSPECTION PROCEDURES USED 87131 & 87132	7. INSPECTION FOCUS AREAS 03.01-03.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02240	2. PRIORITY 2	3. LICENSEE CONTACT James Monroe, PhD - RSO	4. TELEPHONE NUMBER (314) 525-4064
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Main Office Inspection Next Inspection Date: 04/19/2019

Field Office Inspection 10012 Kennerly Road, Suite 300, St Louis, MO

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine 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), and one student at main hospital nuclear medicine department; two full-time and two part-time NMTs at Heart Specialty Associates; and one full-time and one part-time NMTs at PET/CT clinic which was located at main campus. The licensee performed approximately 600+ 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 licensee has not performed any sentinel lymph node biopsy procedures as authorized in the license at 12700 Southfork Road, St Louis, MO since 2011.

The cancer center located at the main hospital was staffed with two oncologists, two authorized medical physicists (AMP), and two dosimetrists. The licensee performed approximately 90 iodine-131 (I-131) hyperthyroid and cancer therapy treatments annually. The licensee conducted approximately six high dose-rate brachytherapy (HDR) gynecological cancer treatments per year. The HDR sources were exchanged quarterly, with the most recent source exchanged on March 13, 2017. The licensee also performed approximately eight Y-90 SIR-sphere treatments and six manual brachytherapy procedures using I-125 for prostate seed implants annually. The licensee has not performed any Ra-223 Xofigo treatments since last inspection. The licensee is planning to build a new cancer center facility by 2018 and planing to move the HDR, PET/CT, and the radiation oncology department to new facility. The new cancer center facility will be located in the main campus. The licensee will submit the blue prints and the amendment request to NRC.

PERFORMANCE OBSERVATIONS

The inspection consisted of interviews with select licensee personnel; review of select records; and tours of the nuclear medicine, PET/CT clinic, and oncology department. The inspector observed administration of Tc-99m doses to a patient for cardiac stress test, with no issues noted.

Continued on next page.

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St. Louis, MO 63128

REPORT NUMBER(S) 2017001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-10108

4. LICENSE NUMBER(S)

24-01041-04

5. DATE(S) OF INSPECTION

April 19 , 2017

(Continued)

The inspector: (1) observed the NMT conduct a physical inventory of sealed sources, and all sources were accounted for; (2) had the NMT demonstrate the dose calibrator constancy check, package receipt and check-in procedures, 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 AMP demonstrate implementation of procedures for Y-90 microspheres as well as the preparation and administration of microsphere injections. The inspector reviewed four HDR, three manual brachytherapy, four I-131 cancer therapy, and two Y-90 microsphere written directives and treatment plans with no issues noted.

The inspector reviewed the following records: radiation safety committee minutes, quarterly program audits conducted by an outside consultant, 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 2015, and till February 28, 2017 indicating the maximum annual dose to be 295 mrem - DDE; and 1250 mrem - SDE. The inspector also reviewed the dosimetry records of two declared pregnant workers since the last inspection. 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.