ENCLOSURE 6 - INSPECTION RECORD

Region: III **Inspection Report No.** 2016001 **License No.** 24-00158-03
Docket No. 030-02269

Licensee: Saint Francis Medical Center
211 Saint Francis Drive
Cape Girardeau, MO 63703

Locations Inspected: Same as above

Licensee Contact: Robert Greyhek, Director of Radiology **Telephone No**. (573) 331-5209

Program Code: 02120 **Priority**: 3

Type of Inspection: ( ) Initial (X) Routine ( ) Announced
( ) Special (X) Unannounced

Last Inspection Date: 04/11/2013 **Date of This Inspection**: 06/23/2016 with in-office review through 07/22/2016

Next Inspection Date: 06/14/2019 (X) Normal ( ) Reduced

Summary of Findings and Actions:

( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
(X) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector Dennis O'Dowd, Health Physicist

/RA/ Date 8/16/2016
Signature

Approved Aaron T. McCraw, Chief, MIB

/ RA Geoffrey Warren Acting for/ Date 8/16/2016
Signature

PART I - LICENSE, INSPECTION, INCIDENT/EVENT AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
68	10/02/2014	Added four authorized users for 35.200 materials and one authorized user for 35.300 materials
69	06/17/2015	Added one authorized user for 35.100 and 35.200 materials
70	03/03/2016	Renewal

2. INSPECTION AND ENFORCEMENT HISTORY:

The last inspection of this licensee was on April 11, 2013. One Severity Level IV violation of NRC requirements was identified. The violation concerned the failure to secure licensed radioactive material, specifically, millicurie quantities of fluorine-18, contained in a MEDRAD Intego PET Infusion System that was stored in the patient injection room from unauthorized access, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 20.1801. There were no violations during the previous two inspections conducted on March 13, 2007, and July 14, 2010.

3. INCIDENT/EVENT HISTORY:

No open items or events since the last routine inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Saint Francis Medical Center is a large medical center with approximately 250 beds. The nuclear medicine department employed four full time technologists who performed 8-9 cardiac stress tests per day, and 8-10 nuclear medicine studies per day using technetium-99m (Tc-99m), including bone, lung, and HIDA scans. The licensee performed thyroid diagnostic studies using 200 microcuries of iodine-123 (I-123). The licensee performed 1-2 thyroid ablations per month using iodine-131 (I-131), and 1-2 whole body scans using four millicuries (mCi) of I-131. All iodine is received in capsule form; no liquid iodine administrations are performed. The nuclear medicine department received unit doses for all scheduled studies, but also received bulk Tc-99m for unscheduled studies. The licensee has one full time technologist who performs 2-3 PET/CT scans per day using fluorine-18 (F-18). The licensee uses the MEDRAD Intego PET Infusion System for delivery of F-18 to the patients.

The licensee receives quarterly visits from its contracted health physicist, who also attends the licensee's radiation safety committee meetings. The nuclear medicine chief

technologist performs the annual audit of the radiation safety program. The radiation safety officer reviews the audit and other nuclear medicine records.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87131

Focus Areas Evaluated: All (03.01- 09)

The inspector observed several administrations of Tc-99m with no issues identified. The licensee's available staff demonstrated/discussed: (1) package receipt surveys; (2) dose calibrator daily constancy, annual accuracy and quarterly linearity checks; (3) daily surveys and weekly wipes; and (4) waste disposal activities. The inspector reviewed I-131 written directives, patient release calculations, and instructions provided to patients prior to being released with no issues identified, with the exception of that described in Item 4 below. The inspector reviewed the following records: (1) dose calibrator; (2) package receipt; (3) daily and weekly surveys; and (3) waste disposal. The inspector reviewed quarterly radiation safety committee meeting minutes and annual audits of the radiation safety program.

The inspector reviewed dosimetry results since the last inspection, and noted that annual whole body and extremity doses were all within exposure limits specified in 10 CFR Part 20.

The technologists were familiar with licensee procedures including spill procedures. The technologists demonstrated a good understanding of radiation safety practices.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector performed dose rate surveys using a Canberra, UltraRadiac, calibrated on November 13, 2015. The inspector performed surveys for contamination using a Ludlum Model 2403 survey meter coupled to a G-M pancake detector, calibrated on April 20, 2016. The inspector conducted independent surveys at each location of use including imaging rooms, hot labs, sealed source storage, and waste storage areas. Survey results were comparable with the licensee's survey data. The inspector found no readings which would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Title 10 of the Code of Federal Regulations (CFR) Section 35.40(a) requires that a written directive must be dated and signed by an authorized user before the administration of iodine 131 (I-131) sodium iodide greater than 1.11 megabecquerels (30 microcuries).

During the inspection, the inspector identified in the review of written directives issued since the date of the previous inspection that a written directive for an administration of 50 millicuries of I-131 sodium iodide to a patient on October 1, 2014, was neither signed nor dated by the Authorized User (AU). The inspector noted that other parts of the form were signed and dated, including pre- and post- treatment verification, and a quality

assurance form review. The inspector confirmed that this failure to have a signed and dated written directive was an isolated case. As this was an administration of I-131 sodium iodide greater than 30 microcuries, the failure of the licensee to ensure that the written directive was signed and dated by the AU prior to proceeding with the administration is a violation of 10 CFR 35.40(a).

The inspector determined that the root cause of the violation was an oversight by hospital staff.

As corrective action, on June 17, 2016, a special training session was held in which the licensee instructed the staff involved in procedures requiring a written directive that they are not to proceed with the administration unless the written directive is signed and properly dated by an Authorized User (AU). On August 1, 2016, the licensee began the use of a revised written directive form which has two separate lines for signature and date, emphasizing the need for the written directive to be signed and dated. Finally, it was noted that the AU who failed to sign and date the written directive is no longer employed at St. Francis Medical Center.

5. PERSONNEL CONTACTED:

* Jordan Gerspner, BSDI, RT(R)(MR), Assistant Manager of Radiology Services
#* Robert Grayhek, MBA, RN, Director of Radiology
Gwen Long, CNMT, Chief, Nuclear Medicine Technologist
#* Greg Rushing, BSHA, CRA, RT(R)(CT), Manager of Radiology Services
Gerry Salter, MBA, PT, Vice President of Professional Services
And other hospital staff

Attended preliminary exit meeting on June 14, 2016.
* Participated in telephone exit meeting on July 22, 2016