Inspection Record

Region III Inspection Report No. 2013-001

License No. 24-00158-03
Docket No. 030-02269

Licensee: St. Francis Medical Center
211 St. Francis Drive
Cape Girardeau, MO

Location Being Inspected: Same as above

Licensee Contact: Trinka Hileman, Director Radiology and Womancare
Telephone No.: 573-331-5209

Priority: 3 Program Code: 2120

Date of Last Inspection: July 14, 2010 Date of This Inspection: April 11, 2013

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

Next Inspection Date: April 11, 2016 (X) Normal ( ) Reduced
Justification for reducing the routine inspection interval:

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 Ken Lambert (Name) Date 5/2/13

Ken Lambert (Signature)

Approved Tamara E. Bloomer (Name) Date 5/2/13

Tamara E. Bloomer (Signature)

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

1. AMENDMENTS AND PROGRAM CHANGES:

AMENDMENT #	DATE	SUBJECT
65	12/19/2010	Added one authorized user for 35.300 radioactive materials, and one authorized user for 35.100, 35.200, and 35.500 radioactive materials
66	07/26/2011	Added PET/CT suite at the licensee's facility
67	09/26/2012	Added SPECT camera suite for cardiac stress tests

2. INSPECTION AND ENFORCEMENT HISTORY:

None - There have been no violations during the last two inspections conducted on March 13, 2007, and July 14, 2010.

3. INCIDENT/EVENT HISTORY:

None - There have been no incidents or events reported to the NRC ince the last inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The licensee was 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 week 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 50 mCi of bulk Tc-99m in the morning and 175 mCi in the afternoon 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: 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. 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 and noted that whole body and extremity doses were 40 millirem (mrem) deep dose equivalent (DDE) and 140 mrem shallow dose equivalent (SDE) for 2013 to February, 3643 mrem DDE and 2582 mrem SDE for 2012, and 336 mrem DDE and 1550 mrem SDE for 2011. Dosimetry results included staff from the nuclear medicine, cardiac stress test, and PET/CT departments. The licensee staff recognized that the DDE doe of 3643 was higher than expected and had reviewed the circumstances surrounding the exposures. The staff determined that the high dose was to an individual who worked in the cardiac stress lab and in the heart catherization lab and received the majority of the dose from fluoroscopy during heart catherizations.

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 January 16, 2013. The inspector performed surveys for contamination using a Ludlum, Model 2403 survey meter coupled to a G-M pancake detector, calibrated on October 17, 2012. Survey results for imaging rooms, hot labs, sealed source storage, and waste storage areas were comparable with the licensee's survey data and within regulatory requirements.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Title 10 Code of Federal Regulations, Part 20, Section 1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. The inspector identified during the inspection that the licensee's mobile MEDRAD Intego PET Infusion System was located in the patient injection room. The licensee began using the infusion system in July 2012, and the system is used and stored in the patient injection room. The injection room door is

operated by push button switches in the hallway and does not have a locking feature. The door is posted with a caution radioactive materials sign. The inspector observed the technologist bring a patient out of the injection room and enter the PET/CT scan room to assist in getting the patient onto the scanner table. While the technologist was assisting the patient, the infusion system, containing 4 mCi of F-18, was left unattended in the unsecured injection room. The licensee's failure to secure from unauthorized removal or limit access to four mCi of F-18 located in the PET/CT patient injection room, which is a controlled area, is a violation of 10 CFR 20.1801.

The licensee's immediate corrective action was to move the infusion system into the locked hot lab. At the time of the inspection, the licensee was still reviewing what, if any, additional corrective actions would be implemented.

5. PERSONNEL CONTACTED:

*Marilyn Curtis, Vice-President Professional Services
*Trinka Hileman, Director Radiology and Womancare
*#Gwen Long, Chief Nuclear Medicine Technologist

Individual present at entrance meeting
* Individuals present at exit meeting