INSPECTION RECORD

Region: III **Inspection Report No.** 2015001 **License No.** 24-08960-02
Docket No. 030-02351

Licensee: St. Mary's Health Center
6420 Clayton Road
St. Louis, MO 63117

Locations Inspected: Same as above

Licensee Contact: David G. Englehart, RSO **Telephone No**. 314-768-8256

Program Code: 02230 **Priority**: 2

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

Last Inspection Date: 08/23/2013 **Date of This Inspection**: 10/20/2015

Next Inspection Date: 10/20/2017 (X) Normal ( ) Reduced

Justification for reducing the routine inspection interval: N/A

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
(X) Followup on previous violations

Inspectors: Deborah A. Piskura, Senior Health Physicist

/RA/ Date 11/23/2015
Signature

Navid T. Tehrani, Health Physicist

/RA/ Date 11/23/2015
Signature

Approved: Aaron T. McCraw, Chief, MIB

/RA/ Date 11/23/2015
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
67	10/15/2014	new AU
66	06/16/2014	new AU
65	02/10/2014	new AU/delete 3 AMPs
64	09/18/2013	3 new AUs

2. INSPECTION AND ENFORCEMENT HISTORY:

The last inspection of this licensee was on 8/23/2013. One violation of NRC requirements was identified involving the failure to perform an evaluation of the TEDE to members of the public from released patients who received therapeutic quantities of I-131 as required by Section 35.75(a). The previous inspection on 08/11/2011 identified no violations of NRC requirements.

3. INCIDENT/EVENT HISTORY:

A review of ADAMS identified no open items. No events had been reported by the licensee since the last routine inspection.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

This was routine inspection of a large community hospital (300 beds) that was authorized to use licensed material permitted by Sections 35.100, 35.200, 35.300, 35.400 and Ir-192 in an HDR afterloader unit. The nuclear medicine department was staffed with two full-time technologists who performed approximately 150-175 diagnostic procedures monthly. The licensee received unit doses and bulk Tc-99m for kit preparation; the department administered a full spectrum of diagnostic studies. The licensee administered numerous I-131 dosages (capsules only) for whole body follow up studies, hyperthyroid, and CA treatments. All patients were released in accordance with Section 35.75. The licensee administered no beta-emitting radiopharmaceuticals since the previous inspection. The licensee retained a consultant who audited the radiation safety program on a quarterly basis.

The radiation oncology department was staffed with one contract AMP, one dosimetrist and one primary authorized physician user. Although authorized for Section 35.400 materials, the licenses had not administered any LDR implants since then previous inspection. The licensee administered approximately 25-30 patient treatments annually utilizing its HDR. The majority of these treatments were for gynecological and breast cancers. All HDR patient treatments were administered by the attending radiation oncologist and the AMP; the AMP operated the controls to the HDR unit. Service, maintenance, and source exchanges were performed by the HDR device manufacturer.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87130, 87131, & 87132

Focus Areas Evaluated: All

This inspection consisted of interviews with licensee personnel, a review of select records, tours of the nuclear medicine and radiation oncology departments, and independent measurements. The inspectors observed licensee personnel perform dose calibrator QA tests, HDR QA and safety checks, inventory of sealed sources, security of byproduct material, and use of personnel monitoring. No diagnostic administrations or HDR patient treatments were observed during this inspection. The inspectors reviewed the written directives and treatment plans for several HDR cases.

The inspectors reviewed the licensee's corrective actions for a violation of Section 35.75(a) cited during the last inspection. Specifically, the licensee failed to perform an evaluation of the TEDE to members of the public from five released patients who received therapeutic quantities of I-131. A review of I-131 patient treatment records revealed that the licensee included calculations for each patient administered a quantity of I-131 in excess of 33 mCi in order to demonstrate the potential TEDE to other individuals resulting from the release of the respective patient. This violation is considered closed.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspectors performed direct radiation measurements in and around the licensee's nuclear medicine hot lab and HDR unit treatment room which indicated similar results as noted in the licensee's survey records. Maximum levels were measured at the surface of the L-block within the hot lab. Radiation levels in the unrestricted areas outside the hot lab, the imaging room, and the HDR treatment room were indistinguishable from background. The inspectors concluded that these radiation levels in the hospital complied with Part 20 limits. All survey measurements in the restricted areas were comparable to the licensee's survey results.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

The inspectors identified one violation of NRC requirements involving the licensee's failure to prevent dual operation of more than one radiation producing device in the HDR treatment room as required by 10 CFR 35.610(a)(3). The inspectors observed that CT simulator was installed and used in the HDR treatment room for patient imaging incident to HDR treatment planning. The inspectors determined that there were no interlocks or other administrative means to prevent dual operation of the CT simulator unit and the HDR unit in the treatment room.

Until approximately Fall 2013, the licensee possessed a different CT simulator unit and utilized a key interlock power switch for the HDR unit and the simulator to prevent dual operation. In the licensee's application dated September 28, 2011, (license renewal), "SSM St. Mary's HDR Daily QA Procedure," the licensee described its interlock power switch and procedure to lock-out the device for operation of the other. In the Fall of 2013, the licensee obtained a new model CT unit. According to the licensee staff, they believed that since an individual needed to physically be in the treatment room to operate the CT unit, no further action was required. The inspectors pointed out and observed that the key to the CT unit remained in the console and the CT remained in operation mode which was contrary to the intent of Section 35.610(a)(3). The inspectors

determined that the cause of the violation was the licensee's misunderstanding of the requirements in Section 35.610(a)(3).

As corrective action, the licensee revised its Policies and procedures to require the AMP to remove the key from the CT unit console prior to initiating an HDR treatment. The licensee verified that removing the key from the CT unit prevented operation of the device. In addition, the licensee revised its daily QA/QC check list to include documentation that the key to the console of the CT was removed prior to operating the HDR unit (for medical use or calibrations and QA/QC checks).

5. PERSONNEL CONTACTED:

#David Englehart, M.S., Radiation Safety Officer
Cindy Kamler, CNMT
#Bob Willard, RT(T), Team Lead, Radiation Oncology
Lindsay Launius-Mobley, M.S., Authorized Medical Physicist
#Kathy Roth, Vice President of Operations
Greg Wunch, CNMT

Attended exit meeting