INSPECTION RECORD

Region: III **Inspection Report No.** 2016001 **License No.** 13-00133-02
Docket No. 030-01579

Licensee: St. Vincent Hospital & Health Care Center

Locations Inspected: Main Hospital, 2001 West 86th Street, Indianapolis, IN
St. Vincent Clay Hospital, 1206 East National Ave., Brazil, IN
St. Vincent Salem Hospital, 911 Shelby Street, Salem, IN
8333 Naab Road, Indianapolis, IN (Cardiac and IVR suites)
10590 North Meridian Street, Indianapolis, IN
13500, North Meridian Street, Carmel, IN

Licensee Contact: Edward E. Wroblewski, RSO **Telephone No**. 317-338-2381

Program Code: 02240 **Priority**: 2

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

Last Inspection Date: April 20-21, 2015, thru June 12, 2015
Date of This Inspection: Feb. 29 – March 3, 2016

Next Inspection Date: Feb 29, 2018 (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
(X) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector: Deborah A. Piskura, Senior Health Physicist

/RA/ Date 3/22/2016
Signature

Approved: Aaron T. McCraw, Chief, MIB

/RA/ Date 3/22/2016
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
147	2/23/2016	delete AUs and AMPs
146	10/07/2015	add new AUs
145	07/30/2015	add TheraSpheres to authorization
144	05/06/2015	new AU

2. INSPECTION AND ENFORCEMENT HISTORY:

On April 20-21, 2015, NRC conducted a reactive inspection, with continued in-office review through June 12, 2015, to review the circumstances of a medical event reported to the NRC on April 13, 2015. The event involved an under dose to the treatment site using the HDR treatment unit for a breast treatment on April 13, 2015. The medical event occurred as a result of damage to the HDR check cable that prevented the licensee from operating its HDR unit and completing the patient's treatment fraction. During the reactive inspection, the licensee informed the inspectors of two additional occurrences of damaged check cables. The licensee send its damaged HDR check cables to the device manufacturer for analysis. Two Open items were identified that required further review: (1) the probable causes of the damaged check cables and any generic implications; and (2) the performance of daily obstruction tests on the HDR unit and any generic implications. The device manufacturer provided the results of its analysis of this damaged check cable in its report dated August 21, 2015.

According to the manufacturer, the manner that the hospital staff performed obstruction tests on the HDR unit using an older model catheter most likely caused the damage to the check cable. The older model catheter has a larger interior diameter that could allow the check cable to bend at a greater angle. In November 2015, the manufacturer issued a bulletin to its customers informing them that obstruction tests on the HDR unit should not be performed by the user. On February 12, 2016, the device manufacturer informed the Region III office that the two remaining damaged check cables (from November 2014 and May 2015 incidents) were presumed lost; the device manufacturer was unable to evaluate these check cables. Based on the results of the inspection and continued review of these issues, no violations of NRC requirements were identified. The licensee ceased performing an obstruction test on its HDR units and to date experienced no additional damaged HDR check cable incidents. The Open Items are considered closed.

A routine safety inspection was conducted on September 16 through 19, 2013, with continued in-office review through October 8, 2013. The licensee's RSO identified one violation of NRC requirements involving use of licensed material by a qualified but unauthorized physician user who was not listed on the license as an authorized user in License Condition 12.B. This licensee-identified and corrected violation was dispositioned as a noncited violation consistent with Section 2.3.3 of the Enforcement Policy.

3. INCIDENT/EVENT HISTORY:

No events had been reported since the previous reactive inspection on April 20-21, 2016. The open items identified during the reactive inspection were closed in letter dated March 9, 2016 (ML16069A221).

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

This licensee was a large medical institution (600+ beds at the main hospital) and conducted licensed activities at 22 locations in Indiana, primarily in the Indianapolis area. The licensee was authorized for materials in Sections 35.100, 35.200, 35.300, 35.400, 35.500, I-125 for temporary seed localization procedures, I-125 in a GliaSite system, Ir-192 in an HDR unit, a Cs-137 calibrator, and Y-90 microspheres. The hospital employed a dedicated full-time RSO, supported by a staff of four physicists and an admin assistant. Collectively, the licensee's nuclear medicine departments were staffed with 20+ FT technologists and PRNs who performed approximately 800-1000+ diagnostic nuclear medicine procedures monthly. Most locations performed a full spectrum of studies and received unit doses and bulk Tc-99m. The main hospital administered numerous I-131 dosages (capsules only) for whole body follow up studies, hyperthyroid, and CA treatments. The main hospital administered 50+ Y-90 SIRSpheres and TheraSpheres treatments annually.

Radiation therapy activities were observed at the main hospital. The radiation oncology department was staffed with 3 contract AMPs, 3 dosimetrists, and 6 authorized physician users. The licensee administered approximately 150+ patient treatments annually utilizing its HDR; these treatments were for breast and gynecological cancer cases. All HDR patient treatments were administered by the attending radiation oncologist and the AMP. Service, maintenance, and source exchanges were performed by the HDR device manufacturer. The department also administered 20-30 Ra-223 Xofigo treatments annually. Although authorized for materials under Section 35.400 (temporary and permanent implants) and the GliaSite system, the licensee had not used this materials since the previous routine inspection. In 2014, the licensee disposed of numerous Cs-137 “tube” brachytherapy sources as well as other long-lived sources through the DOE’s SCATR program.

2. SCOPE OF INSPECTION:

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

Focus Areas Evaluated: All

This inspection consisted of interviews with select licensee personnel; a review of select records; tours of the nuclear medicine and radiation oncology departments; and independent measurements. The inspector observed the licensee's Radiation Safety Committee meeting on April 1, 2016 and the physics staff meeting on April 3, 2016. The inspector observed the licensee staff administer several diagnostic dosages and 2 patient treatments utilizing its HDR unit. The inspector reviewed the patients' written directives and the treatment plans (for HDR cases) and interviewed the attending physician and AMPs. The inspection included observations of source inventories,

HDR safety checks, security of byproduct material, use of personnel monitoring, patient surveys, and package receipt and surveys.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector performed direct radiation measurements in and around the licensee's nuclear medicine hot labs, storage areas, and the HDR treatment suite which indicated similar results as noted in the licensee's survey records. Maximum levels were measured at the surface of the L-block and the fume hood within the main hospital hot lab. Radiation levels in the unrestricted areas outside the hot labs, the imaging rooms, and the HDR treatment suite 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:

One violation of NRC requirements was identified during this inspection involving the failure to secure licensed material at the licensee's Salem, Indiana hospital. The licensee's RSO identified this violation during a routine program audit on February 16, 2016. As the RSO entered the department, he noted that the door to the hot lab/scan room was open and the technologist was not in the area. According to the technologist, she was busy performing multiple tasks and attending to a patient; the room was unsecured for approximately 2 minutes. The inspector reviewed inventory of the licensed material within the hot lab and noted the quantities were less than 1000X App C. The licensee's corrective actions included training the staff on the importance of securing licensed material, writing a "self-identified" violation to the hospital site, and discussing this audit finding during the March 1, 2016, radiation safety committee meeting.

This non-repetitive, licensee-identified, non-willful and corrected violation is being treated as a noncited violation, consistent with Section 2.3.2 of the Enforcement Policy.

5. PERSONNEL CONTACTED:

Will Breeden, III, Diagnostic Physicist
#H. Robin Conners, BSN, JD, CPHQ, Director, Accreditation & Patient Safety
Ryan Couevas, Diagnostic Physicist
Earl Dietrich, M.S., Chief Medical Physicist, Authorized Medical Physicist
Stanley Givens, M.D., Radiation Oncologist
Timothy Greist, M.S., Diagnostic Physicist
#Faud Hammoudeh, FACHE, Executive Director, Cancer Care
Becky Hoberty, Diagnostic Physicist
Christopher A. Leagre, M.D., Radiation Oncologist
Travis Charles Webb, M.S, Authorized Medical Physicist
#Edward E. Wroblewski M.A., Radiation Safety Officer

Numerous nuclear medicine technologists were also contacted during this inspection

Attended exit meeting on March 3, 2016.