INSPECTION RECORD

Region: III **Inspection Report No.** 2018001 **License No.** 13-00133-02
Docket No. 0301579

Licensee: St. Vincent Hospital & Health Care Center
2001 West 86th Street
Indianapolis, IN 46260

Locations Inspected: Main Hospital, same as above
8333 Naab Road, Indianapolis, IN
8301 Harcourt Road, Indianapolis, IN
2020 Meridian Street, Anderson, IN
2015 Jackson Street, Anderson, IN
1907 West Sycamore Street, Kokomo, IN
13420 North Meridian Street, Carmel, IN
13500 North Meridian Street, Carmel, IN
13914 Southeastern Parkway, Fishers, IN

Licensee Contact: Edward E. Wroblewski, RSO **Telephone No**. 317-388-2381

Program Code: 02240 **Priority**: 2

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

Last Inspection Date: 2/29-3/2/16 **Date of This Inspection**: 1/29-2/1/18, with continued in-office review through 2/14/18

Next Inspection Date: 1/29/20 (X) Normal ( ) Reduced

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: Dennis P. O'Dowd, Health Physicist

/RA/ Date 2/22/2018
Signature

Approved: Aaron T. McCraw, Chief, MIB

/RA/ Date 2/23/2018
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
148	03/31/2016	Deleted Authorized Users (AUs)
149	12/20/2016	Added and deleted AUs; added new use location
150	05/23/2017	Added new AU; added new Authorized Medical Physicist (AMP); added Ra-223 authorization for an AU; added new use location; authorized use of Tc-99m at temporary job sites; updated physical inventory license condition
151	09/18/2017	Added new AU; removed use location; added non-medical Tc-99m use authorization
152	01/30/2018	Deleted AUs

2. INSPECTION AND ENFORCEMENT HISTORY:

On November 9, 2017, NRC conducted a reactive inspection, with continued in-office review through January 9, 2018, to review the circumstances of a medical event reported to the NRC on October 28, 2017. No violations were identified as a result of the reactive inspection.

The last routine inspection was conducted from February 29, 2016, through March 3, 2016, and identified one non-cited violation. The violation was licensee-identified involving the failure to secure licensed material, as required by 10 CFR 20.1801. The corrective actions included training the staff on the importance of securing licensed material and discussing the audit finding during the March 1, 2016, Radiation Safety Committee (RSC) meeting.

3. INCIDENT/EVENT HISTORY:

No events had been reported since the reactive inspection on November 9, 2017.

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 23 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, iodine-125 (I-125) for temporary seed localization procedures, I-125 in a GliaSite system, iridium-192 (Ir-192) in an HDR unit, a cesium-137 (Cs-137) calibrator, and yttrium (Y-90) microspheres. The hospital employed a dedicated full-time Radiation Safety Officer (RSO), supported by a staff of four physicists and an administrative assistant. Collectively, the licensee's nuclear medicine departments were staffed with over 30 full-time technologists and PRNs who performed approximately 800-1,000 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 followup studies, hyperthyroidism treatment, and cancer treatments. The main hospital administered over 50 Y-90 microspheres treatments annually.

The radiation oncology department was staffed with 4 contract AMPs, 3 dosimetrists, and 6 physician authorized users. The licensee administered approximately 150+ patient treatments annually using 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 licensee also administered 20-30 radium-223 (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 these materials since the previous routine inspection. As of July 26, 2017, the licensee discontinued the use of I-125 seeds for location of non-palpable lesions under 35.1000.

2. SCOPE OF INSPECTION:

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

Focus Areas Evaluated: All

This inspection consisted of interviews with select licensee personnel; tours of the nuclear medicine and radiation oncology departments; observations of licensed activities; independent measurements; and a review of select records. The inspector observed the licensee staff administer several diagnostic dosages, one Y-90 microspheres treatment, and three HDR patient treatments (two at the main hospital and one at the Anderson facility). The inspector reviewed the written directives and the treatment plans and interviewed attending physicians and AMPs. The inspection included observations of source inventories, HDR safety checks, security of byproduct material, use of personnel monitoring and review of monitoring records, patient surveys, and package receipt and surveys. The inspector observed that a post-treatment SPECT imaging scan was performed on the patient treated with Y-90 microspheres, as per the hospital's standard protocol for all Y-90 treatments, in order to confirm the placement of the microspheres in the liver.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum 2403 survey meter with a model 44-9 energy-compensated GM detector calibrated on October 2, 2017, the inspector performed direct radiation measurements in and around the licensee's various nuclear medicine hot labs, storage areas, and HDR treatment suites that 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 suites were indistinguishable from background. The inspector concluded that these radiation levels in all areas inspected 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 limit failure to limit use a dosage (to a patient) to that within the prescribed dosage range or to a dosage within 20 percent of the prescribed dosage, as required by Title 10 of the *Code of Federal Regulations* (CFR) 35.63(d).

Specifically, on March 31, 2017, a Nuclear Medicine Technologist (NMT) at the licensee's Anderson, Indiana facility, selected the incorrect dose for a myocardial perfusion imaging (MPI) stress dose. A 10-millicurie (mCi) dose of Tc-99m sestamibi was correctly labeled but mistakenly selected for the stress portion of the MPI scan. The NMT meant to retrieve a 30-mCi Tc-99m sestamibi dose. When the NMT assayed the dose in the dose calibrator, the displayed reading was 10.8 mCi (399.6MBq). The NMT then administered the 10.8-mCi dosage of Tc-99m sestamibi to the patient.

Upon realizing that an incorrect dose had been administered to the patient, the NMT informed the RSO. The cardiologist, as well as the referring physician, were also notified on the day of the incident, as was the patient. The patient was re-stressed and a 20-mCi Tc-99m sestamibi stress dose was administered to the patient on the following day. The licensee's standard dosage for the stress portion of an MPI procedure was 20 mCi, when the stress dose is administered on the day following administration of the resting dose.

The licensee's RSO identified this violation upon review on the day of notification (the day the incident occurred) on March 31, 2017.

The licensee's corrective actions included training the staff on the importance of taking time to focus on the tasks being conducted, to not be distracted, especially during times of high-patient workloads, and to slow down to ensure that each dosage is correct to the correct patient, and to be certain to follow the color coding system currently in place at the institution. In addition, the NMT involved with the incident was directed to read and verify each radiopharmaceutical dosage prior to each administration of radioactive material to assure that all dosages are accurately and appropriately administered, was directed to assay each radiopharmaceutical dosage prior to each administration of radioactive material to assure all dosages are accurately and appropriately administered, and directed to have another NMT verify patient radiopharmaceuticals upon assay and kprior to each patient administration for a period of 3 months. The inspector was informed that disciplinary action also was taken. The RSO issued a "self-identified" violation to the hospital site, and the incident, the violation, and corrective actions taken were discussed during the RSC meeting held on June 13, 2017.

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

5. PERSONNEL CONTACTED:

#Jane Berby-Todd, MHA, R.T(R)(T), Manager, Clinical Program – Radiation Oncology & Supportive Care
*Stacy Borden, Administrative Assistant
#William K. Breeden III, M.S., DABR. Diagnostic Radiological Physicist
#H. Robin Conners, BSN, JD, CPHQ, Director, Accreditation and Patient Safety
Ryan Couevas, Physicist Assistant, Nuclear Medicine Technologist
Sandra Crawley, RN, BSN, Director, Cancer Center, St. Vincent Anderson
Earl Dietrich, M.S., Authorized Medical Physicist
Thomas C. Dugan, M.D., Radiation Oncologist/Authorized User
Mathew F. Eastburn, MBA, RT(R), Exec. Director, Diagnostic and Treatment Services, St. Joseph Kokomo
#A. Joel Feldman, M.D., FACS, President, St. Vincent Hospital
Robert C. Gregory, M.S., Authorized Medical Physicist
Stanley Givens, M.D., Radiation Oncologist/Authorized User
Timothy Greist, M.S., Diagnostic Physicist
William Howard, M.S., Authorized Medical Physicist
Becky Hoberty, Junior Physicist
Christopher A. Leagre, M.D., Radiation Oncologist/Authorized User
#Jennifer Martin, RT(R)(CT), Director of Medical Imaging
Brandon K. Martinez, M.D., Interventional Radiologist/Authorized User
Tracy Massey, RN, Oncology Manager, St. Vincent Anderson
Carolyn McCutchen, RT, Director, Medical Imaging, St. Vincent Carmel
Kimberly Nealon, RN, Chief Nursing Officer, St. Vincent Anderson
#Matt Opalka, Nuclear Medicine Supervisor, St. Vincent Indianapolis
#Shawn Rhoton, B.F.A., R.T.(T), Supervisor, Radiation Therapy
#Annie Shaynak, MSN, RN, Director of Outpatient Cancer Services
#Jackie Swaim, Director of Cardiovascular Imaging
Robyn Wargel, RDMS, RVT, RT(R), BA, BS, Manager, Medical Imaging Services, St. Vincent Fishers
Xiaoyang Wang, M.S., Authorized Medical Physicist
Travis Charles Webb, M.S, Authorized Medical Physicist
^Erica Wehrmeister, RN, BSN, MBA, Chief Operating Officer, St. Vincent Hospital
^#*Edward E. Wroblewski, MA, Radiation Safety Officer/Medical Physicist
Alexander Yeh, M.D., Radiation Oncologist/Authorized User

Numerous nuclear medicine technologists, administering treadmill technologists, and ancillary staff were also contacted during this inspection

^ Attended entrance meeting on January 29, 2018.
# Attended the on-site exit meeting on February 1, 2018.
* Participated in the telephonic exit meeting on February 14, 2018.

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