INSPECTION RECORD

Region: III **Inspection Report No.** 2019001 **License No.** 13-00133-02
Docket No. 030-01579

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

Locations Inspected: Main Hospital, same as above
3699 Epworth Road, Newburgh, Indiana
131 South "A" Street, Elwood, Indiana
2015 Jackson Street, Anderson, Indiana
2020 Meridian Street, Anderson, Indiana
03700 Washington Avenue, Evansville, Indiana

Licensee Contact: Edward Wroblewski, Radiation Safety Officer **Telephone No**. 317-755-9688

Program Code: 04822 **Priority**: 2

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

Last Inspection Date: 1/29/2018-2/14/18 **Date of This Inspection**: 10/21/2019-1/23/2020

Next Inspection Date: 10/21/21 (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

Inspectors: Luis Nieves, Health Physicist

/RA/ Date ***02/20/2020***
Signature

Edward Harvey, Health Physicist

/RA/ Date ***02/19/2020***
Signature

Approved: Robert Ruiz, Chief, MIB

/RA/ Date: ***02/20/2020***
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
156	09/17/2019	Removed locations.
155	05/20/2019	Location added.
154	09/20/2019	Authorized User (AU) added, AU removed, new location added
153	05/30/2018	Removed locations.

2. INSPECTION AND ENFORCEMENT HISTORY:

The last routine inspection was conducted on January 29, 2018, with continued in-office review through February 14, 2018, during which one non-cited violation was documented. The violation was licensee-identified and involved the failure to administer the correct dose for a myocardial perfusion imaging stress administration, as required by 10 CFR 35.63(d). The inspector verified that no similar incidents have occurred since this inspection.

On November 9, 2017, the 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.

3. INCIDENT/EVENT HISTORY:

No events had been reported since the last routine inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The licensee was a large medical institution and conducted licensed activities at 19 locations in Indiana, primarily in the Indianapolis area. The licensee was authorized for materials permitted under 10 CFR 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 follow-up studies, hyperthyroidism treatments, and cancer treatments. The main hospital administered over 50 Y-90 microspheres treatments annually.

At the main location, the radiation oncology department was staffed with 4 contract AMPs, 3 dosimetrists, and 6 physician authorized users. The licensee administered approximately 400+ patient treatments annually using its HDR; primarily 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.

At the time of the inspection, the following modalities were used at each location on the license:

2001 West 86th Street, Indianapolis, IN, the license performed 35.100, 35.200, 35.300, Y-90 and HDR treatments;

13500 North Meridian Street, Carmel, IN, the licensee performed 35.100, 35.200, and 35.300 treatments;

1331 South "A" Street, Elwood, IN, the license performed 35.100, 35.200, and 35.300 treatments;

8301 North Harcourt Avenue, Indianapolis, IN, the licensee performed 35.100, 35.200, and 35.300 treatments;

1206 East National Avenue, Brazil, IN, the licensee performed 35.100 and 35.200 studies;

2015 Jackson Street, Anderson, IN, the licensee performed 35.100, 35.200, and 35.300 treatments;

2020 Meridian Street, Anderson, IN, the licensee performed HDR treatments.

1907 West Sycamore Street, Kokomo, IN, the licensee performed 35.100, 35.200, and 35.300 treatments;

8111 Township Line Road, Indianapolis, IN, the licensee performed 35.100 and 35.200 studies;

911 North Shelby Street, Salem, IN, the licensee performed 35.100 and 35.200 studies;

8333 Naab Road, Indianapolis, IN, the licensee performed Y-90 treatments;

10590 North Meridian Street, Indianapolis, IN, the licensee performed 35.100 and 35.200 studies;

13861 Olio Road, Fisher, IN, the licensee performed 35.100 and 35.200 studies;

1116 Millis Avenue, Boonville, IN, the licensee performed 35.100 and 35.200 studies;

1616 Twenty Third Street, Bedford, IN, the licensee performed 35.100, 35.200, and 35.300 treatments;

901 St. Mary's Drive, Evansville, IN, the licensee performed 35.100, 35.200, and 35.300 treatments;

3700 Washington Avenue, Evansville, IN, the licensee performed 35.100, 35.200, 35.300 and Y-90 treatments.

100 Epworth Crossing, Ste. A500, Newburgh, IN, the licensee performed 35.200 studies; and

3699 Epworth Road, Newburgh, IN, the licensee performed 35.200, 35.300, and HDR treatments.

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 inspectors observed the licensee staff administer several diagnostic dosages and two Y-90 microspheres treatments at the main location. The inspectors reviewed the written directives and the treatment plans and interviewed the 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 inspectors observed that a post-treatment SPECT imaging scan was performed on the patients 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 2403 energy-compensated GM detector calibrated on August 30, 2019, the inspectors 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 inspectors concluded that the 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:

Based on the scope of this inspection, no safety violations of NRC regulatory requirements were identified. The inspectors identified two violations of security requirements that are detailed on a separate Security Addendum.

5. PERSONNEL CONTACTED:

Edward Wroblewski - Radiation Safety Officer

Attended exit meeting on January 23, 2020.

Numerous nuclear medicine technologists, Authorize Medical Physicists, and Authorized Users were also contacted during this inspection.

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