ENCLOSURE 6 - INSPECTION RECORD

Region: III Inspection Report No. 2018001 License No. 21-03210-01
Docket No. 030-02028

Licensee: Ascension St. John Hospital
22101 Moross Road
Detroit, MI 48236-2172

Locations Inspected: 22101 Moross Road, Detroit, Michigan (main hospital) and 1901 Star Batt Drive, Rochester Hills, Michigan

Licensee Contact: Laura T. Smith, M.S., RSO Telephone No. 313-317-8848

Program Code: 02240 Priority: 2

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

Last Inspection Date: 5/26/2016 Date of This Inspection: 11/8-9/2018 with continued in office review through 1/25/2019

Next Inspection Date: 1/25/2021 (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: Deborah Piskura, Senior Health Physicist

/RA/ Date: ***02/20/2019***
Signature

Approved: Aaron T. McCraw, Chief, MIB

/RA Michael A. Kunowski for/ Date: ***02/22/2019***
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT

Several amendments were issued to this license since the last routine inspection. Between May 26, 2016 to present, the licensee requested six amendments to its licensee for various program changes including changes/additions of authorized users and medical physicists, locations of use, and a new model of HDR unit,

2. INSPECTION AND ENFORCEMENT HISTORY:

No violations of NRC requirements were identified during the previous two routine inspections on May 26, 2016 and March 3-5, 2014.

3. INCIDENT/EVENT HISTORY:

A review of ADAMS and NMED 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 licensee was a large medical institution and authorized to conduct licensed activities at four locations in the Detroit area. The licensee was authorized for materials in 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, Ir-192 in HDR units, Cs-137 in a self-contained irradiator, and several sealed sources for references and instrument calibration. The hospital employed a dedicated full-time RSO, supported by a designee at each location of use. The licensee's nuclear medicine department at the main hospital was staffed with four full-time technologists, supported by contract part-time technologists, who performed approximately 200-250 diagnostic nuclear medicine procedures monthly; the licensee performed a full spectrum of imaging studies. The licensee received a 6-curie Mo-99/Tc-99m generator weekly for kit preparation. Radiopharmaceutical therapy was limited to I-131 at the main hospital. The main hospital administered numerous I-131 dosages (capsules only) for whole body follow up studies, hyperthyroid, and cancer treatments. The hospital released its I-131 patients in accordance with the provisions of Section 35.75.

Radiation therapy activities were performed at the main hospital and at the licensee’s off-site clinic in Rochester Hills. The radiation oncology department was staffed with five authorized medical physicists, three dosimetrists, and five authorized physician users. The licensee administered approximately 30-40 patient treatments annually. These treatments were for endobronchial, prostate, interstitial, surface and gynecological cancers. 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.

Two violations of NRC requirements were identified during this inspection. One violation involved security-related requirements and is described in the Security Addendum to this report.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: IPs 87130, 87131, and 87132

Focus Areas Evaluated: All

This routine inspection consisted of interviews with licensee personnel, a review of select records, tours of the nuclear medicine, blood bank and radiation oncology departments, and independent measurements. The inspector 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. Several diagnostic administrations were observed during this inspection. The inspection included an in-office review through January 25, 2019, to review and discuss the licensee's package receipt and survey procedures and security-related information provided to the inspector on November 30, 2018, and January 22, 2019.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Survey instrument	Serial No.	Calibration date
Canberra Model UltraRadiac	NRC Tag No. 33569G	07/27/2018

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

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

On November 2, 2018, the radiation oncology department received a "Radioactive Yellow II" labeled package containing approximately 10 curies of Ir-192 as a special form source. After the license staff became aware of the delivery, they secured the package within a locked cabinet inside the HDR treatment room. For reasons that could not be determined, the staff apparently forgot about the receipt of this package and failed to perform the required surveys. The inspector noted there were no records of the surveys and prompted the staff to perform these package surveys. During the installation of the new HDR unit, the device service representative surveyed this package on the afternoon of November 8, 2018, on the licensee's behalf. The licensee's corrective actions included adding an entry to its MOSAIQ therapy tracking software to prompt the staff to survey incoming radioactive packages. The RSO committed to review these surveys during her periodic audits.

Title 10 CFR 20.1906(b) requires each licensee to monitor the external surfaces packages labeled with a Radioactive White I, Yellow II, or Yellow III label for: (1) radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4; and (2) radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Appendix A to Part 71.

Title 10 CFR 20.1906(c) requires licensees to perform the monitoring required by paragraph (b) above, as soon as practicable, but not later than 3 hours after receipt of the package if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

The licensee's failure to perform surveys for radiation levels on a Yellow II package containing 10 curies of Ir-192 within 3 hours after receipt of the package is a violation of 10 CFR 20.1906(c).

5. PERSONNEL CONTACTED:

#Eugene James Boylan, M.S., Authorized Medical Physicist
Jeff Colvin, Ph.D., Authorized Medical Physicist
Laurie Gierc, CNMT, Nuclear Medicine Lead
#Deanna Griebe, Director, Radiology
Carol Hackenberger, M.S., Authorized Medical Physicist
Robert Haddad, Security Chief
#Jenny Hall, MT(ASCP), Manager, Blood Bank
#Robert Hoban, President
#Laurie Lipa, RT(T), Manager, Radiation Oncology
#Brant Russell, Chief Operating Officer
#Teresa Sesiela, RT(R), Radiology Manager
#+Laura T. Smith, M.S., Radiation Safety Officer

Several nuclear medicine and medical technologists were also contacted

Attended the on-site exit meeting on November 9, 2018
+ Attended telephone exit meeting on January 25, 2019.

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