INSPECTION RECORD

Region: III **Inspection Report No.** 2018001 **License No.** 21-04109-16
Docket No. 030-02043

Licensee: Henry Ford Hospital
2799 West Grand Boulevard
Detroit, MI 48202

Locations Inspected: Henry Ford Hospital
2799 West Grand Boulevard
Detroit, MI

Henry Ford Health System Corporate Headquarters
1 Ford Place
Detroit, MI

Licensee Contact: Alan Jackson, RSO **Telephone No**. 734-657-4233

Program Code: 02110 **Priority**: 2

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

Last Inspection Date: January 23, 2017 **Date of This Inspection**: June 11-13, 2018

Next Inspection Date: June 11, 2020 (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

Inspector: Luis Nieves, Health Physicist

/RA/ Date 7/13/2018
Signature

Approved: Aaron T. McCraw, Chief, MIB

/RA/ Date 7/13/2018
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
84	10/05/2017	The purpose was to clarify some points in the license.

2. INSPECTION AND ENFORCEMENT HISTORY:

On February 8, 2017, a reactive inspection was conducted in response to the licensee's report of a medical event. No violations of NRC requirements were identified during this inspection.

The last routine inspection of this licensee was on January 23, 2017. Two security-related violations of NRC requirements were identified during the inspection.

3. INCIDENT/EVENT HISTORY:

The licensee reported a medical to the NRC on February 1, 2017. The medical event, which occurred on January 31, 2017, concerned an yttrium-90 (Y-90) microspheres treatment in which a fraction of the microspheres were delivered to an unintended lobe of the liver. Specifically, a portion of the intended 45-millicurie (mCi) Y-90 microspheres treatment to the left lobe of the patient's liver went to the right lobe of the liver.

The root cause of the medical event is unclear; however, the licensee believes it to be either a potential movement of the catheter caused by an unnoticed patient movement or angiographically undetected reflux caused by the difference in flow dynamics between Theraspheres® and both the contrast agent and Tc-99m macro-aggregated albumin (MAA) used for treatment planning. The licensee stated that the only corrective action to prevent recurrence of a similar event that they could identify would be to exclude patients with challenging vascular anatomy. However, given the rarity of this type of incident and the potential benefits to the treatment, the licensee believes that this action is not viable.

A third party medical consultant, contracted by the NRC, reviewed the circumstances of this medical event and agreed with the licensee's evaluation of: (1) why the event occurred; (2) the effects on the individual who received the unintended dose; (3) the licensee's immediate actions on discovery; and (4) improvements needed to prevent recurrence. The consultant added that patient movements as subtle as breathing may have affected the position of the catheter enough to influence the path of the microspheres within the liver once injected.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The licensee was authorized under NRC Materials License No. 21-04109-16 to conduct medical broad scope activities that included use of licensed material by individuals designated by the licensee's Radiation Safety Committee (RSC). This large medical broad scope licensee had five locations of use in the Detroit, Michigan area.

The licensee's RSC designated individuals as authorized users. Licensed activities included: Y-90 Theraspheres® treatments; iodine-131 (I-131) treatments; Xofigo treatments; high dose-rate remote afterloader (HDR) treatments; diagnostic imaging tests; research and development studies; use of self-shielded irradiators for irradiation of research samples and blood and blood products; and uptake, dilution, and excretion tests. The licensee received technetium-99m generators to perform most of their diagnostic imaging tests.

Although authorized, the licensee had not yet conducted any Y-90 SirSpheres treatments, and had not conduct manual brachytherapy treatments since November 2014. In addition, the licensee had not received a rubidium-82 generator and had no plan to do so.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87126, 87134

Focus Areas Evaluated: 02.01 through 02.07, and 02.09

Theraspheres® Treatments

The licensee conducted about 30 Y-90 Theraspheres® treatments per year. The inspector reviewed a sample of records pertinent to Theraspheres® treatments and interviewed applicable licensee employees to understand how the treatments are planned, administered, and assessed. The inspector noted that the licensee continued to implement its corrective action for the aforementioned medical event. The licensee practiced dual, independent patient identification verification and Theraspheres® dose radioactivity verification prior to treatments. In addition, the licensee conducted radiation surveys pre- and post-administration as a means of determining the amount of radioactivity that was administered to the patient and where.

The inspector observed the preparation and administration of Theraspheres® treatments. An AU and the NMT verified the patient's identify, dose activity compared to the prescribed activity on the written directive, and the licensed material to be administered prior to administration.

HDR Treatments

The licensee conducted about 192 HDR treatments per year, and the majority were gynecology. The inspector observed a treatment, and reviewed the treatment plan and the written directive. The inspector noted that the licensee conducted three independent

patient identifications prior to treatment. The licensee demonstrated daily spot checks of the HDR that day. The inspector reviewed information that verified that the HDR source was as authorized. In addition, the inspector reviewed selected records of recent HDR treatments noting, in part, that the licensee did pre- and post-treatment surveys of the patient's body, and pre- and post-treatment reviews of applicable printouts to determine that the treatments were implemented in accordance with the written directive and the associated treatment plan. The licensee also conducted CAT scans on the patient to verify that the HDR applicator was positioned correctly in the patient's body prior to each HDR treatment fraction. The inspector noted that the licensee implemented action to prevent dual operation of radiation producing equipment.

Nuclear Medicine

The licensee conducted about 32 I-131 administrations and 16 Xofigo administrations per year. The inspector reviewed a sample of records pertinent to I-131 and Xofigo administrations and interviewed applicable licensee employees to understand how the treatments were planned, administered, and assessed. The inspector noted that I-131 patients got pregnancy tests, when applicable, and written and oral radiation safety instructions before their I-131 administrations.

The inspector observed the preparation and administration of a GI bleed and a I-123 uptake. The inspector noted that the NMT wore gloves, a lab coat, and whole body and extremity dosimeter badges. In addition, the NMT used a syringe shield and a shielded syringe carrier to reduce radiation exposure.

Irradiator Safety

The inspector observed that the licensee had an authorized irradiator and observed that an authorized irradiator user (AIU) wore a whole body dosimeter badge. The inspector observed the AIU demonstrate how irradiation of mice or cells were done. The inspector observed that the irradiator room was equipped with a radiation monitor, and observed the AIU demonstrate a successful radiation monitor operability test.

General

The nuclear medicine technologist demonstrated adequate knowledge of radiation safety principles and practices through interviews. The inspector reviewed quarterly audit reports, spill reports, and documentation of package receipt, area surveys, instrument quality control, waste disposal, and employee training. The inspector also reviewed monthly dosimetry reports, which indicated annual whole-body and extremity doses below regulatory limits.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum 2403 survey meter with a model 44-38 energy-compensated GM detector calibrated on January 26, 2018, the inspector conducted independent surveys at the locations inspected. The inspector found no readings that would indicate exposures to members of the public in excess of regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Based on the scope of this inspection, no safety violations of NRC regulatory requirements were identified. The inspector identified a violation of security requirements that is detailed in the non-public Security Addendum to this inspection record.

The inspector reviewed and closed the two security-related violations from the previous routine inspection. Details of the inspectors review of the previous violations are included in the non-public Security Addendum to this inspection record.

5. PERSONNEL CONTACTED:

Alan Jackson – Radiation Safety Officer

Attended exit meeting on June 29, 2018.

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