INSPECTION RECORD

Region: III **Inspection Report No.** 2018001 **License No.** 21-04515-01
Docket No. 030-02051

Licensee: Beaumont Hospital - Dearborn
18101 Oakwood Blvd.
Dearborn, MI 48124

Locations Inspected: Same as above.

Licensee Contact: James Cramb, Manager Imaging Services **Telephone No**. 313-593-7325

Program Code: 02230 **Priority**: 2

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

Last Inspection Date: February 28, 2017 **Date of This Inspection**: December 18, 2018

Next Inspection Date: December 18, 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 2/22/2019
Signature

Approved: Aaron T. McCraw, Chief, MIB

/RA Christine Lipa Acting for / Date 2/25/2019
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
126	10/23/2018	Authorized User (AU) added.
125	06/07/2018	AU added.
124	05/23/2018	AU added and AU taken off.
124	03/23/2018	License name change.
124	03/12/2018	AU added.
123	01/05/2018	AU added.
122	10/09/2017	Y-90 added to license.
122	09/14/2017	AU added.
121	09/12/2017	AU added.
120	06/01/2017	AMP added.
119	04/09/2017	Change of RSO
118	03/21/2017	AU added.

2. INSPECTION AND ENFORCEMENT HISTORY:

On February 28, 2017 a routine inspection was conducted. No violations of NRC requirements were identified during this inspection.

On July 20, 2015 a routine inspection was conducted. Two violations were identified as a result of that inspection. The licensee failed to secure an I-125 seed and failed to give refresher HAZMAT training. Both violations were closed in the February 28, 2017 inspection.

3. INCIDENT/EVENT HISTORY:

On November 27, 2018 an event was reported and then retracted (Event # 53756) for cutting into a I-125 seed when removing it from the tissue sample. The licensee was instructed by the Headquarters Operations Officer (HOO) that cutting into a seed no longer reaches the threshold of a reportable event. Based on this, no violations resulted from this event.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The licensee operated a 600-bed hospital in Dearborn, Michigan, which operated nuclear medicine and radiation oncology departments at the main hospital. Licensed materials were also used in the blood bank. The radiation safety committee overseeing use under the license met at appropriate intervals, had good attendance, and discussed appropriate topics.

The licensee's nuclear medicine department employed nine full-time technologists, who typically performed around 500 diagnostic procedures monthly. These procedures included mostly cardiac stress tests, but included a wide variety of imaging procedures. Doses were received as unit doses from a licensed radiopharmacy. In addition, technologists at this site performed around 17 iodine-131 therapy procedures monthly, occasional radium-223 therapy procedures and eight Y-90 treatments in a year.

The radiation oncology department was staffed with one oncologist, two physicists, and three therapists who were typically involved in licensed activities. Oncology staff performed around seven high dose rate (HDR) remote afterloader fractions, primarily gynecological procedures. The licensee had not performed any brachytherapy implants since 2015. Also the licensee disposed of all their cesium-137 seeds in 2016 but still kept their palladium seeds.

The main hospital blood bank housed the blood irradiator, as described on the license, which was used daily.

At the breast center (18100 Oakwood Blvd.) licensee staff implanted iodine-125 seeds occasionally as temporary implants to localize non-palpable lesions. After implantation, the seeds and surrounding breast tissue were removed in surgery at the main hospital; the tissues and seeds were taken to pathology for analysis. Also at the breast center, licensee staff performed occasional breast lymphoscintigraphy procedures using unit doses of technetium-99m received at this site.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87122, 87131, 87132

Focus Areas Evaluated: All

SIR-spheres Treatments

The licensee conducted about eight Y-90 SIR-spheres treatments per year. The inspector reviewed a sample of records pertinent to Y-90 treatments and interviewed applicable licensee employees to understand how the treatments are planned, administered and assessed. The licensee practiced dual, independent patient identification verification and SIR-spheres 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.

High Dose Rate Afterloader (HDR) Treatments

The licensee conducted about seven HDR treatments per month, and the majority were gynecology. The licensee demonstrated daily spot checks for the HDR. 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 (Computed Tomography) scans on the patient to verify that the HDR applicator was positioned correctly in the patient's body prior to each HDR treatment fraction.

Nuclear Medicine

The licensee conducted about 200 I-131 administrations and three 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 applicable I-131 patients had 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 rest and stress test. 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 Model 26-1 survey meter on October 3, 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 are detailed on a separate, non-public Security Addendum.

5. PERSONNEL CONTACTED:

Donald Conn - Radiation Safety Officer
James Cramb - Manager Nuclear Medicine
Mary Korhs - CNO
Jerry Yang - CFO
Wendy Greenwell - Accreditation and Regulatory Program Manager
Lindsay Vella - Director Imaging
David Claeys – President B

Attended exit meeting on June 29, 2018.

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