INSPECTION RECORD

Region: III **Inspection Report No.** 2016001 **License No.** 21-04080-01
Docket No. 030-02040

Licensee: Mount Clemens Regional Medical Center
1000 Harrington Blvd.
Mount Clemens, MI 48043

Locations Inspected: Location described above
Cancer Center, 1080 Harrington Blvd, Mount Clemens MI
Cardiovascular Institute, 1030 Harrington Blvd, Mount Clemens MI
McLaren Cancer Institute, 5680 Bow Point Dr., Clarkston MI

Licensee Contact: Arthur J. Frazier, M.D., Radiation Safety Officer **Telephone No**. 313-466-8090

Program Code: 02230 **Priority**: 2

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

Last Inspection Date: 01/30/2014 **Date of This Inspection**: January 20 and 21, 2016, with continued in-office review through May 9, 2016

Next Inspection Date: 01/20/2018 (X) Normal ( ) Reduced

Justification for reducing the routine inspection interval: N/A

Summary of Findings and Actions:

(X) 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
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector Geoffrey Warren, Senior Health Physicist

/RA/ Date: 06/06/2016
Signature

Inspector Edward Harvey, Health Physicist

/RA/ Date: 06/06/2016
Signature

Approved Aaron T. McCraw, Chief, MIB

/RA/ Date: 06/09/2016
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
62	Jun. 2015	Add authorized medical physicist (AMP)
61	Apr. 2015	Add additional high dose rate remote afterloader (HDR) model
60	Jan. 2015	Add AMP, remove authorized user (AU)
59	Aug. 2014	Renewal
58	Apr. 2014	Merge license with Macomb Cardiovascular Institute

2. INSPECTION AND ENFORCEMENT HISTORY:

The last two routine inspections were performed in February 2012 and January 2014. No violations were identified during these inspections.

3. INCIDENT/EVENT HISTORY:

Elekta, Inc. (NRC License No. 10-35096-01) reported a stuck source event on August 19, 2015, that had occurred on August 18 at Mount Clemens Regional Medical Center. Hospital staff also reported the event the same day. These notifications were made under 10 CFR 30.50(b)(2) as an event in which equipment is disabled or fails to function as designed.

While hospital staff were performing acceptance testing for a new Flexitron HDR device at the cancer center, the HDR source became lodged in a source position ruler. The hospital had used a microSelectron ruler because the Flexitron source position testing system was not completely installed at the time of testing. The source became lodged after the source passed beyond the ruler and the cable moved sideways into the film channel. When the HDR unit attempted to retract the source, the source became lodged in the film channel.

After it became clear that the source would not retract, hospital staff restricted access to the HDR suite, and worked with Elekta to recover and shield the source. No elevated radiation exposures occurred as a result of the event.

The licensee provided a written report on September 9, 2015. This report, provided under 10 CFR 30.50(c)(2), contained all required information.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The licensee operated four facilities primarily in Mount Clemens, Michigan, with authorization to use byproduct materials in Sections 35.100, 35.200, 35.300, and 35.400, as well as HDR under 35.600. Licensed activities were conducted only at the facilities identified on the license.

The nuclear medicine department at the main hospital was staffed with six nuclear medicine technologists, who typically administered over 400 diagnostic doses monthly. The diagnostic doses included a wide variety of uptake and imaging procedures. The technologists also performed around ten iodine-131 therapy procedures and two radium-223 chloride procedures monthly. Doses were received as unit doses from a licensed nuclear pharmacy.

At the Cardiovascular Institute, two technologists performed around 200 diagnostic imaging procedures monthly, limited to cardiac studies. All doses were received as unit doses from a nuclear pharmacy.

The Ted B. Wahby Cancer Center was staffed with two radiation oncologists, two radiation physicists, and two radiation dosimetrists. These personnel performed around five HDR fractions and three prostate implants using iodine-125 seeds monthly. The prostate implant procedures were performed at the main hospital. The same physics staff performed around two HDR fractions monthly at the McLaren Cancer Institute facility in Clarkston, Michigan.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87131, 87132

Focus Areas Evaluated: 03.01 – 03.08; 03.01 – 03.08

The inspectors observed two diagnostic administrations of licensed material including dose preparation and disposal, an HDR administration including planning and verification, and morning checks in nuclear medicine. Licensee staff demonstrated daily and weekly contamination surveys and other procedures, and described a variety of diagnostic and therapeutic nuclear medicine procedures. The inspectors reviewed written directives for radiopharmaceutical therapies, permanent implant procedures, and HDR procedures. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of personnel exposure records indicated no exposures of regulatory concern.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using calibrated Ludlum 2403 survey meters, the inspectors conducted independent surveys at each of the locations inspected. The inspectors found no readings which would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

The inspectors identified that, in the stuck HDR source event described above, the licensee used the microSelectron source position ruler while doing acceptance testing for a new Flexitron HDR device. This ruler had been neither tested nor approved for use with the Flexitron HDR device. The manual for the Flexitron device states that the user should only connect items to the system which are specified as part of the system or are specified as being compatible with the system. However, the licensee made no commitment to follow the manual for the Flexitron system, so this does not constitute a violation of NRC requirements.

The root cause of the stuck source event was personal error. According to the licensee staff, they were feeling pressured to complete the acceptance testing even though the Elekta engineer had not yet completed installation of the new Flexitron HDR unit. In particular, the engineer had not yet installed the camera inside the Flexitron unit that would be used for source position testing.

5. PERSONNEL CONTACTED:

Praveen Dalmia, Corporate Director, Radiation Services
Branden J. Hill, Lead Technologist, Nuclear Medicine
#* Cindy Scott, RN, OCN, Manager, Radiation Oncology
Mark Yudelev, Ph.D., DABMP, Medical Physicist
And other staff

Attended preliminary onsite exit meeting on January 21, 2016
* Attended telephonic exit meeting on May 12, 2016.