INSPECTION RECORD

Region: III **Inspection Report No.** 2016001 **License No.** 21-32501-01
Docket No. 030-36539

Licensee: West Michigan Cancer Center
200 North Park Street
Kalamazoo, MI 49007

Locations Inspected: Same as above

Licensee Contact: Paul Jursinic, Ph.D, RSO **Telephone No**. (269) 373-7408

Program Code: 02230 **Priority**: 2

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

Last Inspection Date: 04/22/2014 **Date of This Inspection**: 05/23/2016

Next Inspection Date: 05/23/2018 (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: Edward Harvey, Health Physicist

/RA/ Date ***06/14/2016***
Signature

Approved: Aaron T. McCraw, Chief, MIB

/RA/ Date ***06/15/2016***
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
13	11/10/2014	License Renewal
14	04/16/2015	Addition of Authorized User
15	03/01/2016	Addition of Authorized User

The current NRC license expires on November 30, 2024.

2. INSPECTION AND ENFORCEMENT HISTORY:

The last inspection of this licensee was on April 22, 2014. No violations of NRC requirements were identified.

3. INCIDENT/EVENT HISTORY:

No open items or events since the last routine inspection.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

West Michigan Cancer Center (licensee) was authorized under NRC Materials License No. 21-32501-01 to use licensed material for medical use in a Varian Medical Systems, Inc. Model GammaMed plus iX remote afterloading device (HDR). The licensee employed four authorized users and three medical physicists at the time of the inspection. The HDR was used strictly for gynecological procedures at a frequency of approximately 5-10 fractions per week.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87132

Focus Areas Evaluated: All

The inspector observed the conduct of daily spot checks and determined that all of the required checks were performed. The inspector then reviewed a representative selection of written directives and verified that the daily spot checks were performed prior to those treatments by reviewing the corresponding spot check records. Further review of respective treatment plans provided high confidence that the treatments were being performed in accordance with the written directives.

The inspector also observed a fraction of a gynecological treatment and noted that the treatment plan and patient identity were verified prior to administration of the treatment. Additionally, the patient was adequately surveyed prior to leaving the HDR suite. Interviews with the Radiation Safety Officer (RSO) regarding source exchanges,

emergency procedures, equipment checks, and leak tests indicated adequate knowledge of radiation protection principles and NRC requirements.

In addition, the inspector reviewed a selection of licensee records of source exchanges, dosimetry, training, leak tests, and quarterly maintenance with no issues noted.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Canberra UltraRadiac detector, the inspector performed independent measurements around the HDR suite during a treatment and observed no readings that would indicate exposures to members of the public in excess of regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

From January 2009 to May 31, 2016, the licensee failed to provide annual instruction to all individuals who operate the remote afterloader. Specifically, the licensee provided initial instruction to two authorized users who operate the remote afterloader, but failed to complete subsequent instruction at least annually. The RSO explained that he had provided the training material to all pertinent staff every year; however, these particular authorized users failed to complete the training on an annual basis.

As corrective actions for the apparent violation, the RSO: (1) raised the issue to the individual's supervisor, who is also the CEO of the practice; and (2) provided the training for the individuals, which was completed on May 31, 2016.

5. PERSONNEL CONTACTED:

Paul Jursinic, Ph.D., RSO

Attended exit meeting on May 23, 2016.