

INSPECTION RECORD

Region: III

Inspection Report No. 2016001

License No. 21-01549-02

Docket No. 030-02013

Licensee: MidMichigan Health
4000 Wellness Drive
Midland, MI 48670

Locations Inspected: 1) Above Location
2) 4851 E. Pickard Road, Mt. Pleasant, MI

Licensee Contact: Victor Hosfeld, RSO

Telephone No. (989) 839-1407

Program Code: 02240 Priority: 2

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

Last Inspection Date: 07/14/2014

Dates of This Inspection: 10/03/2016 - 10/04/2016

Next Inspection Date: 10/03/2018

(X) Normal () Reduced

Summary of Findings and Actions:

- () No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- (X) Non-cited violation (NCV)
- () Violation(s), Form 591 issued
- (X) Violation(s), regional letter issued
- (X) Follow-up on previous violations

Inspector(s) Edward Harvey, Health Physicist

/RA/
Signature

Date 11/21/2016

Approved Aaron T. McCraw, Chief, MIB

/RA/
Signature

Date 11/21/2016

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
83	08/30/2016	Added Authorized User for 35.100, 35.200, and 35.300.
82	04/07/2016	Relocation of nuclear medicine department within field office.
81	01/25/2016	Change of name and transfer of control.
80	07/29/2015	License renewal
79	05/28/2015	Added authorized user for HDR
78	02/11/2015	Added Authorized User for 35.100, 35.200, and 35.300.
77	12/12/2014	Added authorized user for HDR
76	11/14/2014	Change of RSO and change of Authorized Users
75	05/07/2014	Added location of use and transfer of HDR device

The license expires on June 30, 2025.

2. INSPECTION AND ENFORCEMENT HISTORY:

The last routine inspection of this licensee was on July 14, 2014. During this inspection, one violation of NRC requirements was identified. The inspector verified the licensee's implantation of corrective actions for this violation during the current inspection. This violation is considered closed.

The previous inspection of this licensee was on April 18, 2013. This was a reactive inspection involving a medical event with one violation identified for an isolated failure to implement its written procedure to provide high confidence that each administration was in accordance with the written directive.

3. INCIDENT/EVENT HISTORY:

No open items or events since the last routine inspection.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

MidMichigan Medical Center is a large medical facility in Midland, Michigan authorized under NRC Materials License Number 21-01549-02 to use licensed material for medical procedures. Authorized procedures included diagnostic and therapeutic nuclear medicine, iodine-125 (I-125) prostate seed implants, high dose rate remote afterloader (HDR) treatments, and gamma stereotactic radiosurgery (GSR) treatments. Although authorized, the licensee has not performed any manual brachytherapy procedures authorized under 10 CFR 35.400 since the last inspection. The licensee was authorized

to perform diagnostic nuclear medicine procedures at its facilities in Gladwin, Clare, and Mt. Pleasant, Michigan; and to perform both diagnostic and therapeutic nuclear medicine procedures at its facility in Alma, Michigan. The licensee used a health physics consultant to perform quarterly radiation safety program audits at its nuclear medicine facilities. These audits included leak testing, inventory, quarterly linearity checks of dose calibrators, and annual survey instrument calibration.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87131, 87132, and 87133
Focus Areas Evaluated: All

The inspector performed inspections at the MidMichigan Medical Center located at 4000 Wellness Drive, Midland, Michigan, and at the MidMichigan Health Park located at 4851 E. Pickard Road, Mt. Pleasant, Michigan.

MidMichigan Medical Center

The inspector reviewed the nuclear medicine, HDR, and GSR programs at this location. In the nuclear medicine department, the inspector observed nuclear medicine staff demonstrate package receipt and surveying procedures, daily dose calibrator constancy checks, daily surveys, and waste disposal procedures. All patient procedures scheduled for the day had been completed prior to the start of the inspection; however, the technologists demonstrated adequate knowledge of radiation protection principles and emergency procedures in the event of a spill when explaining the administration process to the inspector. The inspector reviewed a selection of licensee records, including written directives, program audits, dose calibrator linearity records, dose calibrator accuracy records, survey meter calibration records, package receipt logs, and dosimetry, with no issues noted.

In the radiation oncology department, the inspector observed that the HDR unit was secured from unauthorized access. The licensee's staff demonstrated the operational checks performed on the unit prior to use. The inspector reviewed monthly calibration records of the HDR unit and surveys performed after the last source exchange. Discussions with the staff indicated adequate knowledge of emergency procedures and radiation safety principles in the event that the source failed to retract to the shielded position during a patient treatment. The inspector reviewed a selection of written directives and verified that doses delivered to the patients were in accordance with the written directives.

In the GSR Suite, the inspector observed two GSR treatments and noted that an authorized user and medical physicist were present for the treatments. In addition, the inspector observed licensee staff performing operation checks of the GSR unit prior to use. The inspector reviewed records of monthly calibrations, surveys and source exchanges for the GSR unit with no issues noted. The inspector observed that licensee staff verified the patient and treatment protocol for each patient prior to patient treatment. The inspector reviewed a selection of written directives and verified that doses delivered to patients were in accordance with the written directives.

MidMichigan Health Park

The inspector reviewed the diagnostic nuclear medicine program at this facility. All patient procedures scheduled for the day had been completed prior to the start of the inspection; however, the technologist demonstrated adequate knowledge of radiation protection principles and emergency procedures in the event of a spill when explaining the administration process to the inspector. The inspector reviewed a selection of licensee records, including program audits, dose calibrator linearity records, dose calibrator accuracy records, survey meter calibration records, package receipt logs, and dosimetry, with no issues noted.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum 2403 survey meter with a model 44-38 energy-compensated GM detector, the inspector conducted independent surveys at each of the locations inspected. The inspector found no readings that would indicate residual contamination or exposures to members of the public in excess of regulatory limits in unrestricted areas.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

One safety-related violation was identified regarding the licensee's failure to conduct semi-annual inventories in accordance with 10 CFR 35.67(g). However, because the violation was (1) identified by the licensee; (2) adequately corrected by the licensee; (3) not repetitive as a result of inadequate corrective action; and (4) not willful, this violation was dispositioned as a noncited violation.

In addition, the inspector identified one violation of a security-related nature. Details of this violation are discussed in the non-public Security Addendum to this report.

5. PERSONNEL CONTACTED:

- # Matthew Buczek, Medical Physicist
- # Courtney Friedle, Radiation Oncology Manager
- #* Victor Hosfeld, Chief Physicist, RSO
- # Diane Nold, Vice President
- # Dennis Ouillette, Gamma Knife Manager
- # Mike Vanderpol, Imaging Manager
- # Rod Zapolski, Director of Imaging

Attended preliminary onsite exit meeting on October 4, 2016.

* Attended final telephonic exit meeting October 26, 2016.

-END-