INSPECTION RECORD

Region: III **Inspection Report No.** 2019001 **License No.** 21-01549-02
Docket No. 030-02013

Licensee: MidMichigan Health
4000 Wellness Drive
Midland, MI 48670

Locations Inspected: Same as above, including rooms H 1405 and H 1466
515 Quarter Street, Gladwin, MI

Licensee Contact: Victor Hosfeld, RSO **Telephone No**. 989-829-1407

Program Code: 02230 **Priority**: 2

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

Last Inspection Date: 11/08/2018 **Date of This Inspection**: 05/14-17/2019

Next Inspection Date: 05/14/2021 (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 violations (NCVs)
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
(X) Follow-up on previous violations

Inspector: Ryan Craffey, Health Physicist

/RA/ Date ***06/06/2019***
Signature

Approved: Aaron T. McCraw, Chief, MIB

/RA/ Date: ***06/07/2019***
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
87	02/05/19	Notification of intent to relocate nuclear medicine department at Midland location
86	08/07/18	Add, remove AUs; remove AMP
85	08/31/17	Add Alpena location; add AUs
84	11/25/16	Close out old nuclear medicine department at Clare location

2. INSPECTION AND ENFORCEMENT HISTORY:

The last inspection of the licensee was on November 8, 2018. The scope of this inspection was limited to activities at the licensee's Alpena, Michigan location of use. No violations were identified.

The last routine inspection of the radiation safety program was on October 3-4, 2016. One violation of a security-related nature was identified, and a Non-cited Violation (NCV) of Title 10 of the *Code of Federal Regulations* (CFR) 35.67(g) was also noted.

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 Health is a regional medical system authorized by NRC Materials License No. 21-01549-02 to use byproduct material for diagnostic and therapeutic medical purposes at its main campus in Midland, and at satellite facilities in Alma, Alpena, Clare, Gladwin, and Mount Pleasant.

At its radiation oncology department in Midland, the licensee performed around a hundred treatments per year with its Lexsell Perfexion Gamma Stereotactic Radiosurgery (GSR) unit. The licensee had been performing a similar number of treatments with its Varian VariSource iX High Dose Rate Remote Afterloader Brachytherapy (HDR) unit until April 2019, when the licensee temporarily ceased HDR treatments and had the source removed from the unit pending its relocation to an adjacent linear accelerator vault to accommodate the installation of a new accelerator in the original vault. Although authorized for manual brachytherapy treatments, the licensee had not performed any since the last inspection.

At the nuclear medicine department in Midland, three full-time and two-part time technologists performed around a dozen diagnostic administrations per day, Monday through Friday, and a few more each weekend. The technologists also administered a few therapeutic doses of iodine-131 in capsule form each month, as well as one course

of radium-223 Xofigo to date. The licensee was in the final stages of building a new nuclear medicine department at the facility, and was planning to relocate these activities in June 2019.

At its nuclear medicine department in Gladwin, one part-time technologist performed two to four diagnostic administrations per day, Tuesday through Friday.

The licensee maintained a Radiation Safety Committee (RSC), which met quarterly. The licensee also retained the services of an outside health physicist to perform quarterly audits of each nuclear medicine department. The licensee's RSO, its chief medical physicist, was based at the radiation oncology department in Midland.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87131, 87132, 87133

Focus Areas Evaluated: All

The inspector toured all listed locations of use in Midland and the location of use in Gladwin to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector observed numerous diagnostic administrations of radiopharmaceuticals and receipt of packages containing licensed material at the nuclear medicine departments in Midland and Gladwin, as well as one treatment with the GSR unit at the radiation oncology department. The inspector also observed demonstrations of monthly quality assurance checks and implementation of emergency procedures for the GSR unit. The inspector interviewed numerous personnel involved in the radiation safety program to discuss the safe handling and use of radioactive material and to discuss and evaluate program oversight.

The inspector also reviewed a selection of records, including RSC meeting minutes, health physics audits, annual program audits, personnel dosimetry reports, written directives and planning/verification documentation for GSR, HDR, iodine-131 and radium-223 treatments, quality assurance documentation for the GSR and HDR units, source transfer documentation for the HDR unit, instrument calibration records, as well as misadministration and spill reports and other routine nuclear medicine records.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum 2403 survey meter with a model 44-9 GM pancake probe and a Canberra UltraRadiac energy-compensated GM detector, the inspector conducted independent and confirmatory 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. Moreover, the inspector found that the licensee maintained and properly used calibrated, operable survey instruments that were appropriate for the given task.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

During a review of nuclear medicine records, the inspector noted that the licensee had identified a misadministration at the nuclear medicine department in Midland. On August 19, 2018, a technologist performing a gastric emptying study inadvertently

administered approximately 5 millicuries (mCi) of technetium-99m (Tc-99m) mebrofenin instead of the prescribed 0.8-1.2 mCi of Tc-99m sulfur colloid. While hurriedly handling multiple patients, the technologist pulled the wrong unit dose from the shelf while mixing eggs for the study and did not verify its contents before administering it.

Title 10 CFR 35.63(d) states that, unless otherwise directed by an authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

Contrary to the above, on August 19, 2018, the licensee used a dosage of approximately 5 mCi of Tc-99m for a gastric emptying study, that did not fall within the prescribed dosage range of 0.8-1.2 mCi of Tc-99m.

This constitutes a violation of 10 CFR 35.63(d), in accordance with NRC Enforcement Policy example 6.3.D.3. The inspector determined that the root cause of the violation was human error, and noted that the technologist's workload that day appeared to be a contributing factor. As corrective action, the licensee retrained the individual involved, and its health physics consultant performed a dose calculation to confirm that the administration did not meet any criteria to be considered a medical event.

Because (1) the licensee identified the violation; (2) corrected the violation in a reasonable period of time and took additional corrective actions to address the potential for recurrence; and (3) the violation was determined not to be repetitive or willful, the violation met the criteria in Section 2.3.2.B of the Policy and was dispositioned as an NCV.

5. PERSONNEL CONTACTED:

Mel Brown – Nuclear Medicine Technologist
Bryan Crook – Vice President
Victor Hosfeld – Authorized Medical Physicist, Radiation Safety Officer
Matt Johnson – Lead Nuclear Medicine Technologist
Doug Kreis – System Service Line Director
Larry Langrill – Authorized Medical Physicist
Rajnikant Mehta, MD – Authorized User
Danielle Scholes – Nuclear Medicine Technologist
John Urban – Nuclear Medicine Technologist
Mike Vanderpol – Director of Imaging, Midland

Attended exit meeting on May 17, 2019.

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