INSPECTION RECORD

Region: III **Inspection Report No.** 2017001 **License No.** 13-32380-01
Docket No. 030-35963

Licensee: Thyroid and Diabetes Management Center
8939 Broadway
Merrillville, IN 46410

Locations Inspected: same as above

Licensee Contact: Richard S. Longley, M.D., RSO **Telephone No**. 219-736-5077

Program Code: 02200 **Priority**: 3

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

Last Inspection Date: March 16, 2015, with continued in-office review through April 30, 2015

Date of This Inspection: July 27, 2017, with in-office review through August 17, 2017

Next Inspection Date: January 27, 2019 (X) Normal (X) Reduced

Justification for reducing the routine inspection interval: Reduced due to concern with the level of oversight of the radiation safety program.

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: Dennis P. O'Dowd, Health Physicist

/RA by Aaron T. McCraw for/ Date ***09/15/2017***
Signature

Approved: Aaron T. McCraw, Chief, MIB

/RA/ Date: ***09/15/2017***
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
None	N/A	N/A

2. INSPECTION AND ENFORCEMENT HISTORY:

The last routine inspection on March 16, 2015, with continued in-office review through April 30, 2015, identified four violations of NRC requirements resulting in the issuance of Notice of Violation dated May 7, 2015. The previous inspection on March 1, 2012, identified no violations of NRC requirements.

3. INCIDENT/EVENT HISTORY:

No open items or events have been reported by the licensee since the last routine inspection.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The licensee is a private practice physician's clinic authorized to use byproduct material in Section 35.300 for the treatment of thyroid diseases. All patients were released in accordance with the provisions in Title 10 of the *Code of Federal Regulations* (CFR) Section 35.75. The clinic employed one part-time technologist who assisted the authorized user in patient administrations. The licensee obtained its iodine-131 (I-131) dosages in capsule form from an authorized radiopharmacy. Since the time of the previous inspection, the licensee's usage has remained consistent, with two to four patients treated per year. From the period beginning April 28, 2015, to July 28, 2016, the licensee retained the services of a consultant physicist who audited the radiation safety program on a quarterly basis, (with the last audit conducted on July 28, 2016), with recommendations and reminders for various aspects of the program. The licensee has since discontinued the use of the consultant physicist.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87131

Focus Areas Evaluated: All

This inspection consisted of interviews with licensee personnel, a review of selected records, tour of the nuclear medicine department, and independent measurements. On the day of the inspection, no I-131 administrations were performed. Through the inspector's tour of the licensee's facility, the licensee's measures for material security, hazard communication and exposure control were evaluated, with no issues identified. The inspector reviewed a sampling a written directives for I-131 administrations. Each written directive was signed and dated by the authorized user and contained the

required information. The inspector observed that the licensee posted a copy of NRC Form 3. The inspector also observed that the areas where licensed material was used and stored were appropriately posted with "CAUTION-RADIOACTIVE MATERIALS" signs. The hot lab was also posted with emergency/decontamination procedures, and the licensee was able to properly describe the appropriate actions that would be taken in the event of a radioactive material spill.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum 2403 survey meter with a model 44-9 energy-compensated GM detector calibrated on February 24, 2017, the inspector performed direct radiation measurements in and around areas were licensed materials is used or stored. All radiation levels were indistinguishable from background. All survey measurements were comparable to the licensee's survey results.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

The inspector identified four Severity Level IV violations. The last three of which were also identified during the previous inspection.

A. Title 10 CFR 35.60(b) requires licensees to calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions. In accordance with nationally recognized standards and the manufacturer's instructions, the linearity of the licensee's dose calibrator is to be calibrated on a quarterly basis.

   Contrary to the above, as of July 27, 2017, the licensee was using a dose calibrator, an instrument required in paragraph (a) of 10 CFR 35.60, and the linearity of the instrument had not been determined since July 28, 2016, an interval exceeding two or more quarters.

B. Title 10 CFR 35.61(a) requires, in part, that a licensee calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 before first use, annually, and following a repair that affects the calibration.

   Contrary to the above, as of July 27, 2017, the licensee was using a Bicron Surveyor 50 survey instrument to show compliance with 10 CFR Parts 20 and 35, and this survey instrument had not been calibrated since April 26, 2015, a period greater than annually.

C. Title 10 CFR 35.67(b)(2) requires, in part that a licensee in possession of a sealed source shall test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

   Contrary to the above, between January 29, 2017, and July 27, 2017, the licensee failed to test a barium-133 sealed source for leakage, an interval that exceeded 6 months, and no other interval was approved.

D. Title 10 CFR 35.67(g) requires, in part that a licensee in possession of a sealed source shall conduct a semi-annual inventory of all sources in its possession.

Contrary to the above, between January 29, 2017, and July 27, 2017, physical inventories were not performed semi-annually of all sources in the licensee's possession as required.

The root cause of all four violations was a lack of adequate oversight of the radiation safety program. The licensee had relied on its consultant to track and perform these required tasks. However, services were discontinued after the July 2015 consultant audit, and the radiation safety officer (RSO) stated that he had forgotten to monitor the due dates to perform the tasks for the various requirements above. The licensee committed to contacting his former consultant to schedule a site visit/audit; at the time of the exit telephonic meeting, the licensee had attempted to, but had yet to make contact with, the consultant, to resume quarterly program audits. The licensee also stated that arrangements were being made for the survey instrument to be sent out for calibration. The licensee committed to not administering doses further until compliance was restored.

5. PERSONNEL CONTACTED:

Richard S. Longley, M.D., Radiation Safety Officer & Owner

attended preliminary exit meeting on July 27, 2017, and telephonic exit conference on August 17, 2017

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