INSPECTION RECORD

Region: III **Inspection Report No.** 2015-001 **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: **Date of This Inspection**: March 16, 2015, with continued in office review through April 30, 2015, to review and confirm the licensee's immediate corrective actions and the status of the licensee's program

Next Inspection Date: March 16, 2018 (X) Normal ( ) Reduced

Justification for reducing the routine inspection interval:

N/A

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(s) Deborah A. Piskura, Health Physicist

/RA/ Date ***05/06/2015***
Signature

Approved Aaron T. McCraw, Chief, MIB

/RA/ Date: ***05/06/2015***
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
02	10/11/2012	License renewal

2. INSPECTION AND ENFORCEMENT HISTORY:

The last routine inspection on March 1, 2012, identified no violations of NRC requirements. The previous inspection on November 20, 2008, also 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) Part 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. During the past years, the licensee's usage has declined. In 2012, the licensee administered seven treatments. No treatments were administered in 2013 or YTD 2015. The licensee administered one treatment on 5/23/2014. The inspector reviewed the requirements of the decommissioning timeliness rule (10 CFR 30.36) with the RSO. The licensee previously retained the services of a consultant physicist who audited the radiation safety program on a quarterly basis (last on 11/6/2013, with recommendations and reminders for various aspects of the program). At the time of this inspection, the licensee's use was considered inactive; no administrations were performed since May 2014. The licensee could not anticipate future use of RAM but committed to notify the NRC for compliance with 10 CFR 30.36.

Four violations of NRC requirements were identified during this inspection. Through a review of select records and discussions with the licensee, the inspector identified: (1) the licensee had not conducted an annual review of its radiation protection program since 11/6/2013; (2) sealed source leak tests had not been performed at the required 6-month intervals since 11/6/2013; (3) inventory of sealed sources had not been performed at the required 6-month intervals since 11/6/2013; and (4) survey instrumentation had not been calibrated at the required annual intervals since 11/6/2013. The licensee relied on his consultant to track and perform these required tasks on his behalf. However due to lack of payment to the consulting firm, no services were provided since November 2013. The RSO stated that he forgot to monitor the due dates

for the various tasks listed above. The licensee committed to contact his former consultant to schedule a site visit/audit; on April 28, 2015, the consultant resumed the quarterly audits of the program. The consultant confirmed that all tasks listed above had been completed. Refer to section 4 for details on the violations.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87131

Focus Areas Evaluated: All

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 examined the sealed sources in the licensee's possession. Each source container was noted to bear a clearly visible label identifying the radionuclides and source activities. 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.

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.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Survey Instrument Used: Canberra UltraRadiac, NRC Tag No. 33535G
Calibration Date: April 4, 2014

The inspector performed direct radiation measurements in and around the licensee's hot lab including the L-block and waste storage areas. 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:

A. Title 10 CFR 20.1101(c) requires the licensee to periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, between November 6, 2013, and April 28, 2015, the licensee failed to review the radiation protection program content and implementation, an interval that is greater than annually.

This is a Severity Level IV violation (Section 6.3).

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 March 16, 2015, the licensee was using a Bicron Surveyor 2000 survey instrument to show compliance with this part and 10 CFR Part 20, and this survey instrument had not been calibrated from December 12, 2013, through March 16, 2015.

This is a Severity Level IV violation (Section 6.3).

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.

This is a Severity Level IV violation (Section 6.3).

Contrary to the above, between November 6, 2013, and April 28, 2015, the licensee failed to test a barium-133 sealed source for leakage at intervals that did not exceed 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 November 6, 2013, and April 28, 2015, physical inventories were not performed semi-annually of all sources in the licensee's possession as required.

This is a Severity Level IV violation (Section 6.3).

5. PERSONNEL CONTACTED:

Richard S. Longley, M.D., Radiation Safety Officer & Owner
\+ Sharon Updike, Consultant

attended exit meeting
\+ Contacted by telephone

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