



## **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>
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None since last inspection.

### 2. INSPECTION AND ENFORCEMENT HISTORY:

The last routine inspection on July 27, 2017, with continued in-office review through August 17, 2017, identified four violations of NRC requirements resulting in the issuance of Notice of Violation dated September 15, 2017. The previous inspection on March 16, 2015, identified four violations of NRC requirements three of which were repeated violations in the July 27, 2017 inspection.

### 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 Title 10 of the *Code of Federal Regulations* (CFR) 35.300 for the treatment of thyroid diseases. All patients were released in accordance with the provisions in 10 CFR 35.75. The clinic was run by the owner, who also served as the Radiation Safety Officer (RSO). 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. The licensee previously retained the services of a consultant physicist who audited the radiation safety program. However, since the last audit was conducted on November 2017), the licensee had discontinued the use of a consultant physicist again.

#### SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87131

Focus Areas Evaluated: All

The inspector interviewed the RSO, reviewed selected records, toured the nuclear medicine department, and performed independent measurements. On the day of the inspection, no I-131 administrations were scheduled to be performed. The inspector reviewed the licensee's measures for material security, hazard communication, and exposure control, with no issues identified. The inspector reviewed a sample of written directives for I-131 administrations. Each written directive was signed and dated by the authorized user and contained all the required information. The inspector observed that the licensee posted a copy of NRC Form 3.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum GM, Serial No. 316553, calibration date January 26, 2018, the inspector conducted independent surveys at the locations inspected. The inspector found no readings that would indicate exposures to members of the public in excess of regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

The inspector identified three violations. The last two of which were also identified during the previous inspection.

- A. LC 14.A item 9.4 state that all individuals who handle radioactive material on a regular basis will be issued a film, TLD, or OSL whole body monitor

Contrary to the above, since January 2016 to August 9, 2018, the licensee failed to conduct its program in accordance with the procedures established in its license renewal application. Specifically, the owner, RSO, and only person that handles radioactive material on a regular basis was not issued a whole body dosimetry since January 2016.

- B. 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 August 9, 2018, 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 February 2018, an interval exceeding quarterly.

- C. 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 2017, and August 9, 2018, the licensee failed to perform physical inventories of all sources in the licensee's possession semi-annually.

The root cause of all three 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 November 2017 consultant audit. The licensee committed to contract with a different consultant company to reestablish compliance

5. PERSONNEL CONTACTED:

- # Richard Longley – RSO
- # Participated in final exit meeting on July 16, 2019, by telephone.

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