

NRC FORM 591M (04-2022)		U.S. NUCLEAR REGULATORY COMMISSION	
Materials Inspection Report			
1. Licensee/Location Inspected: Thyroid and Diabetes Management Center 8939 Broadway Merrillville, Indiana 46410 Report Number(s) 2022001		2. NRC/Regional Office Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. Docket Number(s) 030-35963		4. License Number(s) 13-32380-01	
		5. Date(s) of Inspection 07/25/2022 - 11/21/2022	
LICENSEE: The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows: <input type="checkbox"/> 1. Based on the inspection findings, no violations were identified. <input type="checkbox"/> 2. Previous violation(s) closed. <input checked="" type="checkbox"/> 3. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy. A. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied. (Non-cited violation(s) was/were discussed involving the following requirement(s) B. The following violation(s) is/are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11. (Violations and Corrective Actions) A. Title 10 CFR 20.1101(c) requires the licensee to periodically (at least annually) review the radiation protection program content and implementation. ...continued on next page			
Statement of Corrective Actions I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.			
TITLE	PRINTED NAME	SIGNATURE AND DATE	
LICENSEE'S REPRESENTATIVE	Richard S. Longley, M.D., RSO	<i>Richard S. Longley</i> 12-19-22	
NRC INSPECTOR	Elizabeth Tindle-Engelmann	Elizabeth D. Tindle-Engelmann <small>Digitally signed by Elizabeth D. Tindle-Engelmann Date: 2022.12.19 08:07:10 -0500</small>	
BRANCH CHIEF	Rhex Edwards	<i>Rhex Edwards</i> <small>Digitally signed by Rhex A. Edwards Date: 2022.12.12 14:00:45 -0500</small>	
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Materials Inspection Report (Continued)

Contrary to the above, between September 10, 2019, and July 25, 2022, the licensee failed to review the radiation protection program content and implementation, an interval that was greater than annually.

As a corrective action the licensee submitted a termination request to the NRC on September 2, 2022 and the license was terminated on October 31, 2022.

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 25, 2022, the licensee was using a Bicron Surveyor 50 survey instrument to show compliance with 10 CFR Parts 20 and Part 35, and this survey instrument had not been calibrated since August 26, 2020, a period greater than annually.

As a corrective action the licensee submitted a termination request to the NRC on September 2, 2022 and the license was terminated on October 31, 2022.

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 June 18, 2020, and July 25, 2022, the licensee failed to test a barium-133 sealed source and a cesium-137 sealed source for leakage, an interval that exceeded 6 months, and no other interval was approved.

As a corrective action the licensee submitted a termination request to the NRC on September 2, 2022 and the license was terminated on October 31, 2022.

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 June 18, 2020, and July 25, 2022, the licensee failed to perform physical inventories of all sources in the licensee's possession semi-annually.

As a corrective action the licensee submitted a termination request to the NRC on September 2, 2022 and the license was terminated on October 31, 2022.

E. License Condition 14.A of NRC Materials License 13-32380-01, amendment 2, states, in part, that the licensee shall conduct its program in accordance with the application dated March 31, 2012. Item 10.12 of the application dated March 31, 2012, states, in part, that all areas where radioactive materials are stored will be surveyed weekly for ambient radiation exposure rates and for removable contamination.

Contrary to the above, from July 23, 2020, to July 25, 2022, the licensee failed to conduct its program in accordance with its license application and established procedures. Specifically, the licensee failed to survey all areas where radioactive materials were stored weekly for ambient radiation exposure rates and for removable contamination.

As a corrective action the licensee submitted a termination request to the NRC on September 2, 2022 and the license was terminated on October 31, 2022.



Materials Inspection Record

1. Licensee Name: Thyroid and Diabetes Management Center		2. Docket Number(s): 030-35963		3. License Number(s) 13-32380-01	
4. Report Number(s): 2022001			5. Date(s) of Inspection: 07/25/2022 - 11/21/2022		
6. Inspector(s): Elizabeth Tindle-Engelmann		7. Program Code(s): 02200		8. Priority: 3	9. Inspection Guidance Used: 87130
10. Licensee Contact Name(s): Richard S. Longley		11. Licensee E-mail Address: no email; fax: 219-736-9316		12. Licensee Telephone Number(s): 219-242-4999	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Non-Routine <input type="checkbox"/> Initial <input type="checkbox"/> Unannounced		14. Locations Inspected: <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Hybrid <input type="checkbox"/> Field Office <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 07/25/2025 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	
16. Location(s) Inspected List: 8939 Broadway, Merrillville, Indiana 46410					
17. Scope and Observations: <p>The licensee was a medical clinic located Merrillville, IN, with authorization for iodine-131 pursuant to 10 CFR 35.300 for outpatient use. At the time of the inspection, the licensee had not conducted principal activities for approximately two years. The licensee's Radiation Safety Officer was the sole Authorized User. From 2018 to 2020, the licensee used an external consultant to perform program reviews and equipment calibrations. From 2018 to July of 2020 the licensee administered approximately 15 iodine-131 sodium iodine dosages. Capsule unit doses were received from a licensed radiopharmacy.</p> <p>The inspector observed a sealed source inventory. The inspector reviewed the following records: calibrations, dosimetry, patient release calculations, package receipt, package return, program reviews, sealed source leak tests and inventories, surveys, training, waste logs, and written directives. The inspector performed independent and confirmatory radiation measurements using a RadEye G (serial number: 30337, calibration expiration: 03/29/2023). Surveys were consistent with the licensee's postings.</p> <p>When the licensee stopped conducting principal activities, they stopped maintaining the consultant services and stopped performing required activities which resulted in the licensee's failure to: (1) periodical review the radiation protection program content and implementation as required by 10 CFR 20.1101(c); (2) calibrate survey instruments used to show compliance with 10 CFR Part 20 and Part 35 as required by 10 CFR 35.61(a); (3) test sealed sources for leakage at intervals not to exceed 6 months as required by 10 CFR 35.67(b)(2); (4) conduct a semi-annual inventory of all sealed sources as required by 10 CFR 35.67(g); and (5) perform surveys in accordance with license conditions.</p>					

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As a result, five violations were identified from this inspection; no previous violations were closed. The licensee transferred possession of their sealed sources to a licensed entity and submitted a license termination request to the NRC on 09/02/2022. On 10/31/2022 the NRC terminated the license. The termination of the license is considered the corrective and preventative action for the violations.

Signature and Date - Branch Chief



Digitally signed by Rhex A. Edwards
Date: 2022.12.12 14:11:04 -06'00'

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Thyroid & Diabetes
Management Center

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To: Elizabeth Tindle-Engelmann From: Dr. Richard Longley
Fax: 630-515-1259 Pages: 6 including cover
Phone: Date: 12/19/22
Re: cc:
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