



Materials Inspection Report

1. Licensee/Location Inspected: Elkhart Clinic 303 South Nappanee Street Elkhart, IN Report Number(s) 2023001	2. NRC/Regional Office Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
--	--

3. Docket Number(s) 03036581	4. License Number(s) 13-32515-01	5. Date(s) of Inspection 8/21/2023 - 8/29/2023
--	--	--

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:

1. Based on the inspection findings, no violations were identified.

2. Previous violation(s) closed.

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)

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		
NRC INSPECTOR	Elizabeth Tindle-Engelmann	Elizabeth D. Tindle-Engelmann <small>Digitally signed by Elizabeth D. Tindle-Engelmann Date: 2023.08.29 12:47:46 -05'00'</small>
BRANCH CHIEF	Rhex Edwards	 <small>Digitally signed by Rhex A. Edwards Date: 2023.09.26 12:05:46 -05'00'</small>



Materials Inspection Record

1. Licensee Name: Elkhart Clinic		2. Docket Number(s): 03036581		3. License Number(s) 13-32515-01	
4. Report Number(s): 2023001			5. Date(s) of Inspection: 8/21/2023 - 8/29/2023		
6. Inspector(s): Elizabeth Tindle-Engelmann		7. Program Code(s): 02121	8. Priority: 5	9. Inspection Guidance Used: 87130	
10. Licensee Contact Name(s): Sherrie White		11. Licensee E-mail Address: swhite@elkhartclinic.com		12. Licensee Telephone Number(s): (574) 296-3200	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		14. Locations Inspected: <input type="checkbox"/> Hybrid <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Field Office <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 8/21/2028 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	
16. Location(s) Inspected List: 303 South Nappanee Street, Elkhart, IN					
17. Scope and Observations: <p>The licensee was an imaging clinic located in the Elkhart, Indiana. The licensee had authorization for diagnostic uses of byproduct material pursuant to 10 CFR 35.200. The licensee's radiation safety officer was a physician Authorized User who was onsite as needed. The licensee utilized a consultant for program reviews, equipment calibrations, and additional oversight of the radiation protection program. The licensee had one full-time nuclear medicine technologist. The licensee's nuclear medicine staff administered approximately 2-4 PET doses per day. Unit doses of fluorine-18 were obtained from a licensed radiopharmacy.</p> <p>The licensee's staff demonstrated decay in storage procedures, package receipt procedures, dose preparation and administration, and package return procedures. Interviews with licensee personnel indicated adequate knowledge of radiation safety and security concepts and procedures. The inspector reviewed the following records: area surveys, dose calibrator calibrations, dosimetry, package receipt, package return, program reviews, sealed source leak tests and inventories, select policies and procedures, shipping records and training.</p> <p>The inspector reviewed the circumstances surrounding EN 56651 / NMED 230315. This event involved the loss of a 300 micro-curie germanium-68 sealed source. The inspector determined that the source was prepared properly by the licensee for shipment. However, the package was subsequently lost in transit by the common carrier. The licensee reported the loss of the source and submitted a written report within the required timeframe. This review closed EN 56651 / NMED 230315.</p> <p>The inspector performed independent and confirmatory radiation measurements using a RadEye G (serial number: 30653, calibration expiration: 05/09/2024).</p> <p>No violations were identified as a result of this inspection.</p>					

Materials Inspection Record (Continued)

Signature and Date - Branch Chief

A handwritten signature in black ink, appearing to be 'R. Edwards', with a long horizontal line extending to the right.

 Digitally signed by Rhex A. Edwards
Date: 2023.09.26 12:05:17 -05'00'