



Materials Inspection Report

1. Licensee/Location Inspected: Radiopharmacy Incorporated 1409 East Virginia Street Evansville, IN 47711 Report Number(s) 2023-001	2. NRC/Regional Office Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. Docket Number(s) 030-31910	4. License Number(s) 13-26246-01MD	5. Date(s) of Inspection December 14, 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	Ryan Craffey	 <small>Digitally signed by Ryan J. Craffey Date: 2023.12.21 08:21:26 -06'00'</small>
BRANCH CHIEF	Rhex Edwards	 <small>Digitally signed by Rhex A. Edwards Date: 2023.12.22 07:17:05 -06'00'</small>



Materials Inspection Record

1. Licensee Name: Radiopharmacy Incorporated		2. Docket Number(s): 030-31910		3. License Number(s) 13-26246-01MD	
4. Report Number(s): 2023-001			5. Date(s) of Inspection: December 14, 2023		
6. Inspector(s): Ryan Craffey		7. Program Code(s): 02500	8. Priority: 2	9. Inspection Guidance Used: IP 87127	
10. Licensee Contact Name(s): Jason Wilson, RPh - RSO		11. Licensee E-mail Address: jwilson@radiopharmacy.com		12. Licensee Telephone Number(s): 812-421-1002	

13. Inspection Type:		14. Locations Inspected:		15. Next Inspection Date (MM/DD/YYYY):	
<input type="checkbox"/> Initial <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		<input type="checkbox"/> Hybrid <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		12/14/2025 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Location(s) Inspected List:

1409 East Virginia Street, Evansville, IN

17. Scope and Observations:

Radiopharmacy Incorporated, a commercial radiopharmacy in Evansville, Indiana, prepared and distributed 300-325 doses of radiopharmaceuticals per day to clients in southern Indiana and Kentucky. The pharmacy primarily prepared unit and bulk doses of Tc-99m using Mo/Tc generators received twice a week. The pharmacy also occasionally prepared unit doses of Ga-68 using a Ge/Ga generator that it shared with other radiopharmacies in the company, as well as unit doses of In-111 and I-123. The pharmacy re-distributed unit doses of positron-emitting radiopharmaceuticals daily, filled I-131 capsules weekly, and re-distributed QC sources and manual brachytherapy seeds on occasion. At the time of the inspection, the pharmacy had five ANPs, three pharmacy techs, and around a dozen drivers. The pharmacy's first run began around midnight with deliveries out by 5:00 am. The second run began around 6:00 am with deliveries starting around 7:30 am. Add-on doses were filled and delivered thereafter.

The inspector toured the facility in Evansville and observed a variety of activities on the pharmacy's second run, including generator elution and breakthrough testing, kit preparation and dose drawing, outgoing package preparation, vehicle loading for transport, return waste handling, and area surveys. The inspector performed independent surveys of restricted and unrestricted areas, and found no evidence of residual contamination or exposures in unrestricted areas above limits to the public. The inspector also performed independent airflow measurements of the licensee's fume hood and glove box for iodine work, and noted flow rates well above minimum requirements. All areas were adequately posted for the hazards present, and all licensed material was adequately secured or under the control and constant surveillance of licensee personnel. The inspector interviewed pharmacists, techs, and drivers, and the licensee's RSO. All personnel implemented effective ALARA practices, wore appropriate dosimetry and PPE, and used calibrated and operable radiation detection instruments.

The inspector also reviewed a selection of records, including program audits, dose calibrator instrument quality control tests, air effluent monitoring and routine area survey results, Ga/Ge generator breakthrough tests, bioassay measurements, and personnel dosimetry reports (maximum 271 mrem DDE / 17498 mrem SDE in 2022, 210 mrem DDE / 19465 mrem SDE in 2023 through 11/9). No violations were identified as a result of this inspection.

Materials Inspection Record (Continued)

Signature and Date - Branch Chief

A handwritten signature in black ink, consisting of a stylized 'R' followed by a horizontal line.

Digitally signed by Rhex A. Edwards
Date: 2023.12.22 07:16:41 -06'00'