

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Radiopharmacy Incorporated 1409 East Virginia Street Evansville, IN 47711 REPORT NUMBER(S) 2021-01		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenton 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 02/17/2021-03/04/2021

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. 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, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(s):

- ☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and 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	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Jason D. Draper	Robert G. Gattone	
BRANCH CHIEF		Michael A. Kunowski	

Digitally signed by Jason D. Draper
Date: 2021.03.04 15:46:47 -06'00'

Digitally signed by Robert G. Gattone
Date: 2021.03.04 15:33:46 -06'00'

Digitally signed by Michael A. Kunowski
Date: 2021.03.05 09:52:00 -06'00'



Materials Inspection Record

1. Licensee Name: Radiopharmacy Inc.		2. Docket Number(s): 030-31910		3. License Number(s) 13-26246-01MD	
4. Report Number(s): 2021-01			5. Date(s) of Inspection: 02/17/2021-03/04/2021		
6. Inspector(s): Bob Gattone and Jason Draper		7. Program Code(s): 02500		8. Priority: 2	9. Inspection Guidance Used: 87127
10. Licensee Contact Name(s): Jason J. Wilson, R.Ph.		11. Licensee E-mail Address: jwilson@radiopharmacy.com		12. Licensee Telephone Number(s): 812-421-1002	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input checked="" type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced		14. Locations Inspected: <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input checked="" type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 02/17/2023 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

This was an announced remote routine inspection. The pharmacy operated Monday through Friday from 12:00 am to 5:00 am, with some regular hours on weekends. The pharmacy distributed 300-350 doses each weekday, primarily on one of two runs. The pharmacy's first run began around 12:30 am with deliveries out by 5:00 am. The second run began around 6:00 am with deliveries out by 11:00 am. In addition to unit and bulk doses of Tc-99m, the pharmacy also compounded In-111 and Tl-201 when necessary, and around six I-131 capsules per week, filled manually. The pharmacy also redistributed Xe-133 gas vials, I-123 capsules, and F-18 FDG unit doses without alteration to its clients. The pharmacy employed four full-time pharmacists, three pharmacy technicians, and around a dozen drivers.

The inspectors: (1) observed photos showing safe use of unsealed radioactive materials; (2) observed photos showing transportation of radioactive materials; (3) observed photos showing a sign stating, "Caution Radioactive Materials"; (3) read records for doses from radiation badges for 2018-2020; (4) read records for I-131 bioassays; (5) read annual audit records 10 CFR 20.1101(c) for 2018 - 2020; (6) read dose calibrator accuracy tests; (7) read sealed sources inventory records; (8) read sealed source leak test records; (9) read COMPLY records dated 1/26/2021 and 2/23/2021 for I-131; (10) read records dated 2/1/2021 - 2/23/2021 for I-131 "Monitoring Summary" with no issues; (11) noted that the licensee had a fume hood with charcoal filters including the filter exchange procedure; (12) read "Area Wipe Summary Report" in areas of the facility; and (13) observed G.M. survey results in the facility.