



Materials Inspection Report

1. Licensee/Location Inspected: NukeMed, Inc., dba SpectronRx 9550 Zionsville Rd. Indianapolis, IN 46268 Report Number(s) 2023001	2. NRC/Regional Office Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. Docket Number(s) 030-38044	4. License Number(s) 13-32726-01MD	5. Date(s) of Inspection July 21, 2023
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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	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman <small>Digitally signed by Zahid M. Sulaiman Date: 2023.08.14 17:13:24 -05'00'</small>
BRANCH CHIEF	Rhex Edwards, Chief, MIB	 <small>Digitally signed by Rhex A. Edwards Date: 2023.08.17 07:45:28 -05'00'</small>



Materials Inspection Record

1. Licensee Name: NukeMed, Inc., dba SpectronRx		2. Docket Number(s): 030-38044		3. License Number(s) 13-32726-01MD	
4. Report Number(s): 2023001			5. Date(s) of Inspection: July 21, 2023		
6. Inspector(s): Zahid Sulaiman, Health Physicist		7. Program Code(s): 02500	8. Priority: 2	9. Inspection Guidance Used: 87125	
10. Licensee Contact Name(s): John Zehner, RPh, RSO Valerie White, ARSO		11. Licensee E-mail Address: jzehner@spectronrx.com vwhite@spectronRX.com		12. Licensee Telephone Number(s): Work: 317-459-8315 Work: 765-775-0451	

13. Inspection Type:		14. Locations Inspected:		15. Next Inspection Date (MM/DD/YYYY):	
<input type="checkbox"/> Initial <input type="checkbox"/> Routine <input type="checkbox"/> Announced <input checked="" 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		<input type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input checked="" type="checkbox"/> No change	

16. Location(s) Inspected List:
Main office: 9550 Zionsville Rd. Indianapolis, IN 46268

17. Scope and Observations:

This was an unannounced non-routine inspection of a contract radiopharmaceutical manufacturer in Indianapolis, Indiana. The inspection was conducted to review the licensee's corrective actions taken in response to escalated enforcement action (EA-22-065) involving a violation of 10 CFR 30.3(a), for possession of sealed sources containing Radium-226 (Ra-226) but was not authorized by its NRC license for this radioisotope.

The licensee's corrective actions included: (1) returning the radium-226 to properly authorized individuals; (2) requesting an amendment to your NRC license for the possession of radium-226, which was subsequently approved by the NRC; (3) radiation safety officer's acknowledgment of awareness and understanding of the licensing requirements for radium-226; (4) hiring a law firm to review the circumstances surrounding the violation and provide advice regarding the difference between radioactive materials licensed by a State and those licensed by the NRC; and (5) planning to seek information from the NRC when pursuing to add any new radioactive materials to confirm whether NRC or State licensing is required. The inspector reviewed the licensee's implementation of its corrective actions and confirmed that these actions, listed above, had been completed in accordance with its commitments in letter dated September 1, 2022 [ML22262A062].

No violations of NRC requirements were identified as a result of this inspection. The violations identified during the previous inspection (03038044/2022001(DNMS)) are considered closed.

Signature and Date - Branch Chief



Digitally signed by Rhex A. Edwards
Date: 2023.08.17 07:44:55 -05'00'