NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
NukeMed Inc., dba SpectronRx	030-38044 / 030-38045	13-32726-01MD / 13-32726-02

4. Report Number(s):	5. Date(s) of Inspection:
2021-001	April 5-25, 2021

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Ryan Craffey	02500 / 03210	2	IP 87126, 87127

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
John Zehner, RPh	jzehner@spectronrx.com	574-271-2800

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial	☑ Main Office ☐ Field Office	04/05/2023
☑ Routine ☑ Announced	☐ Temporary Job Site ☑ Remote	☑ Normal ☐ Extended
☐ Non-Routine ☐ Unannounced		☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced routine inspection of a contract radiopharmaceutical manufacturer in South Bend, Indiana, authorized to prepare and distribute radioactive drugs and radiochemicals for medical and non-medical use, to use radioactive material for R&D purposes, to produce and distribute radioactive material using a cyclotron, and to possess incidentally-activated products. At the time of the inspection, the licensee routinely prepared and distributed radiolabeled monoclonal antibodies containing I-131, Lu-177 and Ac-225 and diagnostic radiopharmaceuticals containing In-111 to support clinical trials and investigational new drugs for brain and prostate cancer treatments. The week before the inspection, the licensee received authorization to use material at a new location in Indianapolis; it intends to expand production operations to this new facility in the near future. The licensee had not used its cyclotron in South Bend for isotope production since 2019; however, it continued to possess and store material incident to production there and intends to resume production with the machine in the near future as well.

The inspector toured the facility in South Bend to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent and confirmatory radiation surveys and airflow measurements throughout the facility in restricted and unrestricted areas, observed a radiosynthesis procedure involving I-131 and subsequent QA activities, and reviewed the licensee's use of air monitoring equipment, area survey equipment, and personnel monitoring equipment with emphasis on equipment and procedures for bioassay. The inspector also reviewed the licensee's response to elevated staff bioassay measurements recorded since the last inspection. The inspector concluded that while these readings were well below regulatory limits on intake and exposure, the licensee's response to them, including enhanced radiation monitoring and analysis, additional air handling and filtering equipment, increased management oversight, and additional staff training and engagement nevertheless demonstrated a strong commitment to maintaining occupational and public exposures ALARA.

The inspector also reviewed with staff and management the licensee's measures for contamination control, waste handling, radiation safety training, and a selection of program records. Prior to the on-site inspection, the inspector remotely reviewed program audits, dosimetry reports, material inventories, sealed source leak test results, instrument calibration records and waste disposal documentation. During the on-site inspection and thereafter, the inspector also reviewed additional air monitoring, area survey and bioassay results, as well as staff training materials.

No violations of NRC requirements were identified as a result of this inspection. The inspector held an exit meeting with the licensee's management on April 25, 2021.