NRC FORM 592M
(10-04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

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

4. Report Number(s):	5. Date(s) of Inspection:
2026001	4/8/2026-5/28/2026

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Laura Dresen	03210 / 02500	2	87125, 87127

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Jon Bolen Eric Lester, Site Manager	JBolen@spectronRx.com Elester@spectronRX.com	574-261-8917 708-308-7968

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☐ Routine ☑ Announced ☑ Non-Routine ☐ Unannounced	☐ Hybrid ☑ Main Office ☐ Field Office ☐ Temporary Job Site ☐ Remote	12/20/2026 ☐ Normal ☐ Extended ☐ Reduced ☑ No change

16. Location(s) Inspected List:

17490 Dugdale Drive, South Bend, IN 46635

17. Scope and Observations:

This was a limited scope inspection of the licensee's production of a clinical trial drug for a clinical study. This inspection was conducted as a result of a patient overexposure event reported by BAMF on April 2, 2026, from the administration of the drug that was produced by Spectron RX at its South Bend facility. Following the event report, the production of any further patient doses was cancelled and all further doses were required to be produced as research/non-clinical.

The inspector met with and interviewed the South Bend licensee's Director of Manufacturing Services, three pharmacists and the QC Manager. The current production was one dose per run with two to three doses shipped per week. The inspector discussed with the licensee staff the process for producing the clinical drug, how batches for both non-clinical use and clinical use were produced and handled, the collection of QC results, and the shipping and/or disposal of product.

The inspector toured the facility to include the room designed for the sole production of these products. The inspector also reviewed the specs required for the production of the drug. At the time of the inspection, this was the only product being produced by SpectronRX for this research company. This product was required to be produced via elution from a thorium-228 generator provided by the company. The inspector interviewed a pharmacist on the various aspects of generator receipt, set-up, and operation. All source material needed for the production of the drug was supplied by the Department of Energy, ordered by the company and shipped directly to SpectronRX. SpectronRX would store the source material until needed for production. When the company requested the production of the product, they would identify the specific source material that was previously provided, to be used in the production run. The radio-pharmaceutical produced was required to be produced as 99% pure lead-212 (Pb-212) with an impurity less than or equal to 1% verified using a High-Purity Germanium (HPGe) spectrometer. The inspector reviewed the HPGe results for all clinical doses, a total of eighteen (18) doses, produced and shipped for administration. All clinical doses met the requirements of 99% purity with the lowest purity of clinical doses produced

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to have a 99.5% purity.

The inspector reviewed the following licensee documents:
Standard Operating Procedure GEN 1210 Rev B, Title: Release Criteria for Th-228/Pb-212 Generator Source Holder
Standard Operating Procedure GEN 1204 Rev C, Title: Radionuclidic Identity and Purity by HPGe Gamma Spectrometry for 212Pb and 228Th
Standard Operating Procedure QMS 2904 Rev A, Title: .Radionuclidic Identity, Radionuclidic Purity and Impurity by HPGe Gamma Spectrometry for [the clinical drug] Final Drug Product
Standard Operating Procedure QMS 2910 Rev A, Title: Release Criteria of [the clinical drug] Final Drug Product

The inspector found the licensee was producing the product per the specifications required by the research company and agreed upon by SpectronRX.

No violations of NRC requirements were identified as a result of this inspection. The U.S. Food and Drug Administration, who oversees the research study, is continuing to review this event.

Signature and Date - Branch Chief

GEOFFREY WARREN Digitally signed by GEOFFREY WARREN
Date: 2026.06.10 06:46:25 -05'00'