NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Hot Shots Nuclear Medicine	030-38407	21-32812-01MD

4. Report Number(s):	5. Date(s) of Inspection:
2022-001	May 19, 2022

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

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Allen Doan, PharmD - RSO	a.doan@hotshotsnm.com	906-869-1759

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial	☑ Main Office ☐ Field Office	05/19/2024
☑ Routine ☐ Announced		☑ Normal ☐ Extended
☐ Non-Routine ☑ Unannounced	☐ Temporary Job Site ☐ Remote	☐ Reduced ☐ No change

16. Scope and Observations:

This commercial radiopharmacy in Marquette, Michigan, prepared and distributed 100-130 unit doses of Tc-99m radiopharmaceuticals per day to clients in the Upper Peninsula of Michigan. The licensee had two authorized nuclear pharmacists, two pharmacy technicians, and eight drivers. The pharmacy's first run began by 1:00 am with doses out by 3:30 am. The second run began by 8:00 am with doses out by 9:00 am. The pharmacy received generators every Monday for preparing unit and bulk doses of Tc-99m. The pharmacy also prepared occasional In-111 and Tl-201 doses, re-distributed I-123 and I-131 capsules, and was planning to begin using Ge-68/Ga-68 generators in the near future.

The inspector toured the facility in Marquette and observed a variety of activities on the pharmacy's second run, including generator elution and breakthrough testing, kit preparation and dose drawing, radiopharmaceutical quality control, outgoing package preparation, and vehicle loading for product transport. The inspector performed independent surveys of restricted and unrestricted areas, and found no evidence of residual contamination or exposures to members of the public in excess of regulatory limits. The facility, occupied by the licensee since November 2021, matched the description provided in the licensee's amendment request dated January 19, 2021. All areas were adequately posted, and all licensed material was adequately secured or under control and constant surveillance of licensee personnel. The inspector interviewed the licensee's RSO, other pharmacist, technologists, and drivers. All personnel implemented adequate ALARA practices, wore appropriate dosimetry and PPE, and used calibrated and operable radiation detection instruments effectively.

The inspector reviewed a selection of records, including program audits, dose calibrator and multi-channel analyzer quality control records, survey meter calibration records, hazmat training documentation, weekly bioassay results (no detectable uptakes since the last routine inspection), and occupational dose reports, which indicated maximum doses from licensed activities of 257 mrem DDE / 19,782 mrem SDE to the extremities in 2020, and 232 mrem DDE / 15,499 mrem SDE to the extremities in 2021.

No violations of NRC requirements were identified as a result of this inspection.