



Materials Inspection Report

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| 1. Licensee/Location Inspected: Hot Shots Nuclear Medicine 3145 Wright Street Marquette, MI 49855 Report Number(s) 2024-001 | 2. NRC/Regional Office Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352 | |
| 3. Docket Number(s) 030-38407 | 4. License Number(s) 21-32812-01MD | 5. Date(s) of Inspection May 30, 2024 |

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 | Ryan Craffey | <small>Digitally signed by RYAN CRAFFEY Date: 2024.06.06 09:41:12 -05'00'</small> |
| BRANCH CHIEF | Rhex Edwards | <small>Digitally signed by RHEX EDWARDS Date: 2024.06.07 10:26:51 -05'00'</small> |



Materials Inspection Record

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| 1. Licensee Name: Hot Shots Nuclear Medicine | | 2. Docket Number(s): 030-38407 | | 3. License Number(s) 21-32812-01MD | |
| 4. Report Number(s): 2024-001 | | | 5. Date(s) of Inspection: May 30, 2024 | | |
| 6. Inspector(s): Ryan Craffey, Daniel Fiedorek | | 7. Program Code(s): 02500 | 8. Priority: 2 | 9. Inspection Guidance Used: IP 87127 | |
| 10. Licensee Contact Name(s): Allen Doan, PharmD - RSO | | 11. Licensee E-mail Address: a.doan@hotshotsnm.com | | 12. Licensee Telephone Number(s): 906-869-1759 | |
| 13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced | | 14. Locations Inspected: <input type="checkbox"/> Hybrid <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Field Office <input type="checkbox"/> Remote | | 15. Next Inspection Date (MM/DD/YYYY): 05/30/2026 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change | |
| 16. Location(s) Inspected List: 3145 Wright Street, Marquette, MI | | | | | |
| 17. Scope and Observations: This commercial radiopharmacy in Marquette, Michigan, prepared and distributed around 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 4:00 am. The second run began by 8:00 am with doses out by 9:30 am. The pharmacy received Tc-99m generators every Monday and routinely used a Ge-68/Ga-68 generator as well. The pharmacy also prepared occasional In-111 doses and re-distributed I-123 and I-131 capsules to clients. The inspectors 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 inspectors also observed demonstrations of staff bioassay and reviewed the licensee's method of determining internal exposure. The inspectors 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. All areas of the facility were adequately posted, and all licensed material was adequately secured or under control and constant surveillance of licensee personnel. The inspectors interviewed the pharmacist, technologist, and several drivers. All personnel implemented adequate ALARA practices, wore appropriate dosimetry and PPE, and used calibrated and operable radiation detection instruments. The inspectors reviewed a selection of records, including program audits, dose calibrator and multi-channel analyzer quality control records, area survey results, driver training documentation, weekly bioassay results (which indicated maximum internal doses of less than 3 mrem annually), and occupational dose reports (which indicated maximum external doses of 176 mrem DDE / 15,193 mrem SDE to the extremities in 2022, and 178 mrem DDE / 12,270 mrem SDE to the extremities in 2023). No violations of NRC requirements were identified as a result of this inspection. | | | | | |

Materials Inspection Record (Continued)

Signature and Date - Branch Chief

A handwritten signature in black ink, consisting of a stylized 'R' followed by a horizontal line.

Digitally signed by RHEX EDWARDS
Date: 2024.06.07 10:26:25 -05'00'