

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Hot Shots Nuclear Medicine 2296 US Hwy. 41 S Marquette, MI 49855 REPORT NUMBER(S) 2019001		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 22, 2019	

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:

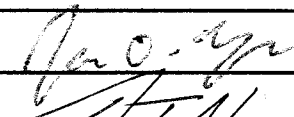
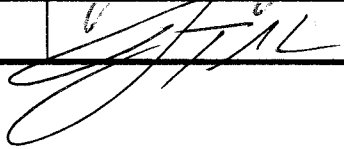
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(s):

- 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and 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	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Jason D. Draper, Health Physicist		5/22/19
BRANCH CHIEF	Aaron T. McCraw		6/4/19

Docket File Information
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6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS 03.01-03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Allen R. Doan, PharmD, RSO	4. TELEPHONE NUMBER (906) 273-1306
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Main Office Inspection Next Inspection Date: 05/22/2021

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of a radiopharmacy outside Marquette, Michigan that served the Upper Peninsula of Michigan. The licensee was authorized to use byproduct material to prepare radiopharmaceuticals for use by nuclear medicine licensees for medical procedures. At the time of the inspection, the radiopharmacy operated Monday through Friday starting at 12:30am with deliveries starting around 2:30am and weekend operations as needed. The licensee employed one full-time Authorized Nuclear Pharmacist who compounded approximately 60-100 doses of primarily Tc-99m radiopharmaceuticals per day, as well as prepared occasional I-131 capsules for diagnostic studies. The licensee also employed 7 drivers. The licensee's radiation safety program was reviewed quarterly by a corporate representative.

PERFORMANCE OBSERVATIONS

The inspector toured the radiopharmacy to observe material security, postings, and any other potential hazards to the material. The inspector also performed independent surveys of restricted and unrestricted areas and did not identify any contamination or dose rates that could cause members of the public to exceed regulatory limits. The inspector observed a variety of activities including dose preparation, outgoing package preparation, package surveys, and delivery vehicle loading. The ANP also described the licensees procedures for air effluent monitoring and bioassays for personnel preparing I-131 capsules. The inspector reviewed a selection of records associated with dosimetry, area surveys, equipment checks and calibrations, license verification, training records, effluent monitoring reports, and audits, and no issues were identified.

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