

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Hot Shots Nuclear Medicine 2296 U.S. 41 South Marquette, Michigan 49855 REPORT NUMBER(S) 2017001		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 June 22, 2017	

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:

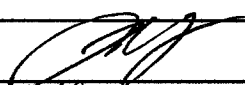
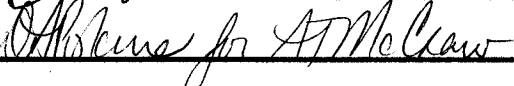
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Luis Nieves Folch		6/22/2017
BRANCH CHIEF	Aaron T. McCraw		7/21/17

Docket File Information
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6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS 03.01-03.08
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02200	2. PRIORITY 2	3. LICENSEE CONTACT Allen R. Doan, Pharm.D., RSO	4. TELEPHONE NUMBER (906) 273-1306
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Main Office Inspection Next Inspection Date: June 22, 2019

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of a radiopharmacy. This site, located in Marquette, MI, routinely served the Upper Peninsula of Michigan. The pharmacy operated Monday through Friday, with limited hours on weekends. The pharmacy distributed around 100 doses each weekday, primarily in one of four runs. The first run began around 2:15am, second at 2:35 am, third at 2:45 am, and 4:00 am. In addition to compounding doses of technetium-99m and other common isotopes, the pharmacy also compounded 5-6 iodine-131 capsules each week. The licensee had one Authorized Nuclear Pharmacist and RSO, and 10 drivers on staff at the time of the inspection.

Performance Observations

The inspector toured the facility to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent surveys of restricted and unrestricted areas, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The inspector observed a variety of activities during the licensee's first run, including dose preparation, outgoing package preparation, client package return and waste handling, generator elutions and, area surveys and delivery vehicle loading. The licensee's staff also demonstrated the implementation of procedures for air effluent monitoring and bioassay for personnel preparing I-131 capsules. Through these observations, demonstrations and other discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements.

The inspector reviewed a selection of records, including audits, ALARA and incident reports, dose calibrator quality control records, air effluent monitoring reports, survey meter calibration certificates, hazmat training records, and dosimetry reports.

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

Handwritten signature and date:
7/21/17