NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Hot Shots Nuclear Medicine 2296 U.S. 41 South Marquette, Michigan 49855 REPORT NUMBER(S) 2015-001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38407	21-32812-01MD	October 6, 2015

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 violations(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	Dennis P. O'Dowd	Dennis P. O'Dowd	10/06/15
BRANCH CHIEF	Aaron T. McCraw		11/4/15

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87127	03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	Allen R. Doan, Pharm.D., RSO	(906) 273-1306

☑ Main Office Inspection Next Inspection Date: 10/06/2017

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced inspection of a nuclear pharmacy located in Marquette, MI, serving Michigan's Upper Peninsula. The nuclear pharmacy staff included one pharmacist, one pharmacy technician, and nine drivers. The licensee received two generators each week, and prepared and distributed an average of 90-100 unit doses per weekday. In addition to unit doses, the pharmacy occasionally distributed I-123, and I-131 capsules, therapeutic beta emitters, and In-111 blood labeling. The pharmacy does not compound I-131; it is ordered by the pharmacy from a vendor and "passed through" to the pharmacy client that had ordered the dosage. There was no change in unit dose production since the previous inspection. Unit dose production starts around midnight and ends at approximately 3:30 am each weekday. The pharmacy is also open from 8:00 am to noon to take orders for the next day.

Performance Observations

The inspection consisted of interviews with select licensee staff, comprehensive facility tour, direct observations, independent measurements, and a review of select records. In interviews, the RSO and other available licensee personnel indicated an adequate knowledge of radiation safety concepts, as well as emergency and material handling procedures and techniques, provided through recurring training. Licensee staff demonstrated/discussed and record reviews included, the following, with no issues identified: (1) unit dose prep and safe use procedures; (2) package returns and breakdown procedures; (3) area and contamination surveys; (4) DOT packaging and transportation procedures; (5) generator elutions and tests; (6) wipe test counting and efficiency procedures; (7) survey instruments and calibrations; (8) postings and labeling; (9) staff training; (10) annual radiation safety program audits and periodic corporate audits; (11) waste handling; (12) facility security; (13) dose calibrator tests; (14) sealed source inventories and leak tests; (15) any transportation events involving a loss of control of licensed material (none); and (16) doses to licensee personnel: the highest cumulative weekly and monthly dosimetry records indicated for: 2013:168 mrem DDE (whole body) and 25,362 mrem SDE (extremity); 2014: 265 mrem DDE and 20,192 mrem SDE; 2015 through August: 222 mrem DDE and 8813 mrem SDE. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings, and which indicated no readings in excess of 10 CFR Part 20 limits in restricted and unrestricted areas. Licensed material was observed as adequately secured during the review and was not readily accessible to members of the public.

No violations were identified during this inspection.