

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

CPI Pharmacy Services Holding, LLC
d/b/a Hot Shots Nuclear Medicine
3960 Patient Care Drive, Suite 105
Lansing, MI 48911

REPORT NUMBER(S) 2015-001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-33629

4. LICENSE NUMBER(S)

21-26597-01MD

5. DATE(S) OF INSPECTION

NOVEMBER 18TH, 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:

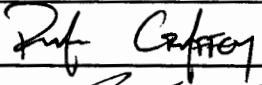
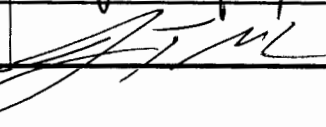
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Ryan Craffey		11/18/15
BRANCH CHIEF	Aaron McCraw		11/25/15

Docket File Information

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6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS All
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Matthew D. Kazmierski, RPh - RSO	4. TELEPHONE NUMBER (517) 887-3131
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Main Office Inspection Next Inspection Date: 11/18/2017

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of a radiopharmacy in Lansing, Michigan, which routinely served around 20 clients a day across southern Michigan. The pharmacy operated Monday through Friday from midnight until 5:00 pm, with limited morning hours on weekends. The pharmacy distributed around 400 doses each weekday, primarily on one of two runs. The first run began around 1:00 am, with deliveries out between 3:00 am and 5:30 am. The second run began around 6:30 am, with deliveries out by 9:00 am. The pharmacy compounded additional doses for local hospitals as necessary through the afternoon. The licensee primarily compounded unit doses of Tc-99m along with other radionuclides as necessary. The licensee also compounded a handful of I-131 capsules per week manually using a glove box. The licensee had three Authorized Nuclear Pharmacists on staff, as well as four technologists and five to six drivers on staff daily. The licensee's VP of Operations conducted quarterly audits of the radiation safety program.

PERFORMANCE OBSERVATIONS: The inspector toured the facility in Lansing to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent surveys of restricted 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 following the licensee's first run, including generator elution, dose preparation, outgoing package preparation, client package return and waste handling, area surveys and delivery vehicle loading. The licensee's staff also demonstrated the implementation of procedures for I-131 capsule preparation and air effluent monitoring. Through these observations, demonstrations, and additional discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements.

The inspector reviewed a selection of licensee records for dose calibrator quality control, hazmat training, annual radiation program audits, and personnel dosimetry, which indicated maximum exposures in 2014 of 43 millirem (mrem) whole-body / 30280 mrem extremity, and 22 mrem whole-body / 31342 mrem extremity in 2015 through September 4th. The inspector noted the increase in extremity dose, which was due primarily to the increased workload of the morning pharmacist, and discussed with the licensee its measures to ensure that occupational limits would not be exceeded, as well as potential measures to improve ALARA practices.

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