

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

CPI Pharmacy Services Hosting, LLC
d/b/a Hot Shots Nuclear Medicine
3960 Patient Care Dr.
Lansing, Michigan 48911

REPORT NUMBER(S) 2018001

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

March 1, 2018

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:

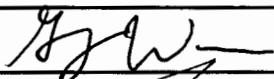

- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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	Geoffrey Warren, Sr. HP		3/8/18
BRANCH CHIEF	Aaron McCraw		3/8/18

Docket File Information**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

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3. DOCKET NUMBER(S) 030-33629	4. LICENSE NUMBER(S) 21-26597-01MD	5. DATE(S) OF INSPECTION March 1, 2018
6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS 03.01 - 03.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Matthew Kazmierski, RSO	4. TELEPHONE NUMBER (517) 887-3131
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<input checked="" type="checkbox"/> Main Office Inspection	Next Inspection Date: 3/1/2020
<input type="checkbox"/> Field Office Inspection	
<input type="checkbox"/> Temporary Job Site Inspection	

PROGRAM SCOPE

This was an unannounced routine inspection. This radiopharmacy employed 3 pharmacists, 6 pharmacy technicians, and 9 drivers. The licensee distributed approximately 400-450 doses each weekday to around 40 regular customers located in southern Michigan. The pharmacy was open weekdays from 11:30 pm through 5:00 pm, with limited hours on weekends. The licensee's scheduled runs started at 1 am, 6:30 am, and 11:30 am, with doses for each run leaving by 4:30 am, 9 am, and 1 pm, respectively. The licensee received four Mo-99/Tc-99m generators each week for preparation of Tc-99m doses. Xenon-133 gas vials and iodine-125 capsules were received and redistributed to customers. The pharmacy compounded I-131 therapy capsules for distribution. All iodine-131 material was manipulated and stored in a glove box. While authorized, the licensee had not yet begun redistributing yttrium-90 microspheres.

The licensee's corporate office conducted an annual audit of the program. The maximum dose received by licensee personnel in calendar year 2016 was 56 mrem whole body and 41 rem extremity, in calendar year 2017 was 86 mrem whole body and 40 rem extremity, and in January 2018 was 11 mrem whole body and 3.1 rem extremity.

Performance Observations: The inspector observed generator elution, molybdenum checks, kit preparation, QA sampling and analysis, dose drawing and packaging, use of long-handled tools for handling materials, dose survey and wipe, package preparation and verification, DOT surveys, package blocking and bracing, shipping paper placement, package return surveys, and other procedures. Licensee staff demonstrated iodine-131 compounding, indium-111 blood labeling, package receipt surveys and wipes, and area surveys, and described waste disposal, inventory, audit, and other procedures. Drivers interviewed indicated boxes containing licensed material would not be left in unsecured areas. Review of dosimetry records indicated no exposures of regulatory concern. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

No violations were identified during this inspection.

Warren, Geoffrey

From: Warren, Geoffrey
Sent: Thursday, March 08, 2018 9:38 AM
To: 'm.kazmierski@hotmail.com'
Subject: NRC Inspection Report
Attachments: NRC 591M - CPI Pharmacy 2018001.pdf

Enclosed is the inspection report for the NRC's inspection last week at your facility in Lansing, Michigan. As we discussed on Monday, no violation is being cited in this report. No response is required to the report or to this message.

In accordance with Title 10 of the Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this message and its attachment will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>.

Please feel free to contact me if you have any questions regarding this correspondence.

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Geoffrey Warren
Senior Health Physicist (Inspector)
NRC Region III
630-829-9742