NRC FORM 591M PART 1
(10-2011)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
CPI Pharmacy Services Holding, LLC d/b/a Hot Shots Nuclear Medicine 3960 Patient Care Drive Lansing, Michigan 48911 REPORT NUMBER(S) 11-001	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
030-33629	21-26597-01MD	November 15, 2011

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)

NMED Item Nos. 110560, 110562 (closed)

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 M. Warren		11/17/11
BRANCH CHIEF	Tamara E. Bloomer		11/18/11

NRC FORM 591M PART 3
(10-2011)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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030-33629	21-26597-01MD	November 15, 2011

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	Matthew D. Kazmierski, R.Ph., RSO	(517) 887-3131

☑ Main Office Inspection Next Inspection Date: Nov. 2013

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This radiopharmacy employed 3 staff pharmacists, 6 pharmacy technician, and 9 drivers. The licensee had approximately 100-150 regular customers located in southern Michigan, and distributed approximately 400 to 500 doses each weekday. The pharmacy was open weekdays from 11:00 p.m. to 5:00 p.m., with limited hours on weekends. The licensee's first weekday run was from 1 a.m. through 5:30 a.m., the second run was from 6:30 a.m. through 9:00 a.m., and further deliveries were made as needed throughout the day. The licensee received Mo-99/ Tc-99m generators each week for preparation of technetium-99m doses. Xenon-133 gas vials were received and redistributed to their customers; the inner containers were not opened in the pharmacy. The pharmacy compounded iodine-131 therapy capsules containing less than 100 mCi for distribution; capsules containing 100 mCi or more were ordered from offsite and redistributed. All iodine-131 material was manipulated and stored in a glove box, which had a dedicated exhaust system.

The licensee had a consultant perform annual external audits of the radiation safety program. The maximum dose received by licensee personnel in calendar year 2010 was 235 mrem whole body and 37138 mrem extremity; and from January through September 2011, the maximum was 255 mrem whole body and 23926 mrem extremity.

Performance Observations

During this inspection, the inspector observed generator elution, molybdenum checks, kit preparation, QC sampling and analysis, dose preparation and tracking, package surveys and wipes, shipping paper preparation, package blocking and bracing, disposal of returned syringes, waste tracking and disposal, use of personal protective equipment and dosimetry, equipment decontamination, area surveys, and other activities. Licensee personnel demonstrated dose calibrator constancy, package receipt surveys, iodine-131 capsule preparation, and other activities. The inspector noted no concerns with these activities. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry and survey records showed no evidence of doses of concern to radiation workers or general public. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

(continued on Part 2, attached)

NRC FORM 591M PART 2
(10-2011)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-33629	21-26597-01MD	November 15, 2011

(Continued)

From Part 3/Program Scope:

The inspector reviewed NMED Item No. 110560 and No. 110562 concerning packages sent from this pharmacy and received at client hospitals. The hospitals identified contamination above DOT limits on the packages. The inspector reviewed licensee survey records and observed staff performing package surveys and wipes, and did not identify any clear indication that the contamination occurred at the pharmacy. The RSO stated that they had not determined the cause of the contamination, but that he had taken actions to reduce the likelihood of sending contaminated packages in case the packages had been contaminated at the pharmacy. These actions included retraining staff on package survey techniques and making an increased effort to observe package surveys to ensure that procedures were followed. This closes the two NMED items.

TRANSMISSION VERIFICATION REPORT

TIME : 11/17/2011 04:45
NAME : USNRC REGION3 DNMS
FAX : 6305151259
TEL :
SER.# : 000A7J925770

DATE,TIME	11/17 04:45
FAX NO./NAME	15178873132
DURATION	00:00:32
PAGE(S)	02
RESULT	OK
MODE	STANDARD ECM

NRC FORM 386 (RIII)
(4-2004)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 11/17/11

NUMBER OF PAGES: *(including this page)* 2

SEND TO: Matthew D. Kazmierski, R.Ph., RSO

LOCATION: CPI Pharmacy Services Holding, LLC

FAX NUMBER: 517-887-3132 ☐ ***VERIFY BY CALLING SENDER***

FROM: *(SENDER)* Geoffrey Warren, Health Physicist

TELEPHONE NUMBER: **630**-829-9742 FAX NUMBER: **630**-515-1259

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE

Enclosed is the inspection report we discussed.