NRC FORM 591M PART 1
(10-2010)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE	
Medi Physics, Inc. dba GE Healthcare 1623 Lotsie Blvd. Overland, Missouri 63132 REPORT NUMBER(S) 2012001	Region III: 2443 Warrenville Rd., Ste. 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36453	24-32462-01MD	Oct. 17 , 2012

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. 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 M. Warren		10/17/12
BRANCH CHIEF	Tamara E. Bloomer		10/24/12

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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Medi Physics, Inc. dba GE Healthcare 1623 Lotsie Blvd. Overland, Missouri 63132 REPORT NUMBER(S) 2012001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

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030-36453	24-32462-01MD	October 17, 2012

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	Peter Mullady, R.Ph., RSO	(314) 733-0471

☑ Main Office Inspection Next Inspection Date: October 2014

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This radiopharmacy employed three pharmacists, two pharmacy technicians, and five drivers. The licensee had seven regular customers located in eastern Missouri and southwestern Illinois, and distributed approximately 80 doses each day. The pharmacy was staffed weekdays from 3:00 am through 4:00 pm, with limited hours on weekends. The licensee's first weekday run was performed from 4:00 through 5:00 am; the second run was performed from 6:45 through 8:00 am, and doses were prepared and delivered as needed after the second run. The licensee received Mo-99/ Tc-99m generators twice weekly for preparation of unit doses and bulk technetium-99m. Xenon-133 gas vials and iodine-125 solution were received and re-distributed to customers. The pharmacy compounded iodine-131 (I-131) therapy capsules for distribution. All I-131 material was manipulated and stored in a glove box. The pharmacy occasionally prepared and distributed unit doses of indium-111, iodine-123, yttrium-90, and other isotopes, and performed indium-111 white blood cell labeling. The licensee's corporate office conducted an annual audit of the program and the RSO conducted a quarterly in-house audit. The maximum exposure received by licensee personnel in calendar year 2011 was 35 mrem whole body and 8.5 rem mrem extremity, and from January through August 2012, the maximum was 62 mrem whole body and 4.4 mrem extremity. The laboratory area had been renovated as described to NRC to enclose dose preparation areas in a clean room.

Performance Observations

The inspector observed generator elution, kit preparation and QC, molybdenum assay, dose preparation and wipes, package surveys and wipes, shipping paper preparation, package labeling, blocking and bracing, package return surveys, waste handling, daily surveys, and decontamination of clothing. Licensee personnel demonstrated dose calibrator constancy, I-131 capsule preparation, white blood cell labeling, and daily surveys, and described emergency, bioassay, and training procedures and control of the preparation area during renovation. The inspector noted no concerns with these activities. The inspector observed proper usage of personal whole-body and extremity dosimetry, as well as the use of long-handled tools to reduce doses. Review of dosimetry and survey records indicated no exposures of regulatory concern to radiation workers or members of the public. 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.