

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Medi Physics, Inc. d/b/a GE Healthcare 1623 Lotsie Boulevard Overland, MO 63132 REPORT NUMBER(S) 2018001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532	
3. DOCKET NUMBER(S) 030-36453	4. LICENSE NUMBER(S) 24-32462-01MD	5. DATE(S) OF INSPECTION April 13, 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	Zahid Sulaiman, Health Physicist	<i>Zahid Sulaiman</i>	5-10-2018
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB	<i>ATM</i>	5/10/18

Docket File Information

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

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Peter Mullady, R.Ph., RSO	4. TELEPHONE NUMBER (609) 514-6647
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Main Office Inspection Next Inspection Date: 04/13/2020
 Field Office Inspection _____
 Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine inspection of a radiopharmacy authorized under NRC license to prepare and distribute diagnostic and therapeutic radiopharmaceuticals to approximately 26 clients in the St. Louis area. The licensee was staffed with three authorized nuclear pharmacists, two pharmacy technicians, and four drivers. The radiopharmacy's first run began around 2:00 am with deliveries out by 5:00 am; the second run began around 8:00 am and out by 10:00am; and additional runs were made as needed throughout the day. The licensee received two Mo-99/Tc-99m generators each week for preparation and distribution of unit doses and some bulk Tc-99m. The licensee received and redistributed Xe-133 gas vials. The licensee compounded iodine-131 capsules inside a ventilated hood. The licensee occasionally prepared and distributed unit doses of Tl-201, In-111, and Ga-67.

Performance Observations

The inspection consisted of interviews with select licensee personnel; a review of select records; a tour of the facility; and independent measurements. The inspector observed a variety of activities on the licensee's second run, including generator elution, molybdenum breakthrough evaluation, kit preparation, dose drawing, client package preparation, DOT package labeling and vehicle loading, as well as client package return and waste handling. The inspector had the staff demonstrated area surveys, I-131 capsule preparation, ventilation hood air monitoring and filter change out procedures, spill response, and decay-in-storage waste handling. Interviews with licensee staff and demonstrations indicated that licensee staff were knowledgeable of radiation protection principles and regulatory requirements. The inspector observed that staff wore the assigned dosimetry ring and body badge, wore gloves and protective clothing while handling radioactive materials, and monitored their hands and feet for contamination before exiting the restricted area. The inspector reviewed the dose calibrator constancy, linearity, and accuracy; air monitoring, area survey, decay-in-storage waste disposals, DOT hazmat training, internal and external program audits, bioassay results, sealed source inventory, and leak test reports. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with the licensee's survey results and within regulatory limits. The inspector reviewed the dosimetry records for 2016, and till February 28, 2018, indicating the maximum annual dose to be 0.18 rem - DDE; and 12.674 rem - SDE.

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