NRC FORM 591M PART 1
(07-2012)
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 12300 Hubbard Road Livonia, MI 48150 REPORT NUMBER(S) 2017001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-29642	21-24828-01MD	May 23, 2017

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)

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	Zahid Sulaiman	5/23/17
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		6/14/17

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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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	Bradley Ambs, R. Ph., RSO	(734) 425-0425

☑ Main Office Inspection Next Inspection Date: 05/23/2019

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine unannounced inspection of a radiopharmacy authorized under NRC license to prepare and distribute diagnostic and therapeutic doses to clients, primarily in the Detroit and northwestern Ohio areas. The licensee was staffed with four authorized nuclear pharmacists, six pharmacy technicians, and eight drivers. The radiopharmacy's first run began around 1:00 AM with deliveries out by 5:00 AM; the second run began around 6:30 AM and out by 12:00 PM; and additional runs were made as needed throughout the day. The licensee distributed approximately 400-500 doses daily. The licensee receives four Mo99/Tc99m generators each week for preparation and distribution of unit doses and some bulk technetium-99m. The licensee occasionally prepares and distributes unit doses of Tl-201, In-111, and Ga-67. The licensee did not compounded I-123 and I-131 capsules at this facility. The licensee received and redistributed Xe-133 gas vials, I-123 and I-131 in capsules form from outside vendors. The licensee did not prepare or distribute any beta-emitting therapy doses.

Performance Observations:

The inspection consisted of interviews with select licensee personnel; review of select records; a tour of the facility; and independent measurements. The inspector observed 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 licensee's staff demonstrated the implementation of procedures for area surveys, ventilation hood air monitoring and filter change out procedures, and decay-in-storage waste handling. The inspector observed the staff followed the proper procedures to go in and out of the clean room. The inspector observed staff monitored their hands and feet for contamination before exiting the restricted area. The inspector had a pharmacy technician demonstrate spill response on a given spill scenario. The licensee staff was knowledgeable of the regulatory requirements. The licensee's corporate office and the site radiation safety officer conducted independent annual audits of the program. The inspector reviewed the corporate and RSO audit reports, dose calibrator quality control, survey records, I-131 air monitoring report, decay-in-storage waste disposals, DOT hazmat training, sealed source inventory, and leak test reports. The inspector also reviewed the dosimetry records for 2016 till February 2017, indicating the maximum annual dose to be 183 mrem-DDE, and 16,507 mrem-SDE. The inspector performed independent and confirmatory radiation measurements that indicated results consistent with the licensee's survey results and within regulatory limits.

No violations of NRC requirements were identified during this inspection.