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 Rd. Livonia, MI 48150 REPORT NUMBER(S) 2019001	NRC Region III 2443 Warrenville Rd., Suite 210 Lisle, IL 60532 Select a location (Use keyboard arrows to select). . .

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-29642	21-24828-01MD	4/4/19

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	Robert G. Gattone, Jr.	Robert G. Gattone, Jr.	4/4/19
BRANCH CHIEF	James T. McGraw		4/12/19

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Medi-Physics, Inc. dba GE Healthcare 12300 Hubbard Rd. Livonia, MI REPORT NUMBER(S) 2019001	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
030-29642	21-24828-01MD	4/4/19

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87127	03.01 through 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	Bradley Ambs, ANP, RSO	(248) 640-9849

☑ Main Office Inspection Next Inspection Date: 04/04/2021

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced inspection of a radiopharmacy authorized under its 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 5:00AM; the second run began around 6:30AM 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 received Xe-133 gas vials and I-123 capsules from outside vendors. The licensee did not prepare or distribute any beta-emitting therapy doses. The licensee began compounding Iodine-131 capsules and solutions in February 2019.

Performance Observations

The inspector: (1) reviewed records of the licensee's annual radiation protection program audit records for 2017 and 2018; (2) reviewed records of dosimeter badge readings for 2017, 2018, and 2019 through 1/31/19, and the extremity and whole body doses were well below the annual dose limits; (3) reviewed selected sealed source inventory records; (4) reviewed selected sealed source leak test records; (5) observed an authorized nuclear pharmacist (ANP) demonstrate how he compounded Iodine-131 capsules using a Drax Image Smart Fill Dispensing System (DISFDS); (6) noted that the DISFDS and the fume hood effluent air was sampled with a charcoal filter, and an ANP demonstrated how he sampled the air effluents weekly including use of the COMPLY code and the licensee complied at Level 2; (7) observed an ANP prepare a kit for Technetium-99m Myoview; (8) noted that the licensee did not put licensed material down the sanitary sewer system; (9) observed licensee staff handling licensed material while wearing appropriate personal protection equipment; (10) observed licensee staff handling licensed material while wearing dosimeter badges; (11) observed an ANP demonstrate how he conducted I-131 bioassays; (12) reviewed selected records of area surveys; (13) used an NRC-owned, calibrated survey meter to conduct independent, ambient exposure rate surveys at selected surfaces in the restricted area, and there were no concerns; and (14) reviewed selected HAZMAT training records. No violations of NRC regulatory requirements were identified as a result of this inspection.