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. d/b/a GE Healthcare 4380 Brockton SE, Suite 3 Kentwood, MI 49512 REPORT NUMBER(S) 2017001	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
030-34090	21-26707-01MD	May 26, 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	Ryan Craffey	Ryan Craffey	05/26/2017
BRANCH CHIEF	Aaron McCraw		06/15/2017

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	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	Stephen M. Williams, R.Ph. - RSO	(616) 554-5717

☑ Main Office Inspection Next Inspection Date: 05/26/2019

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine inspection of a radiopharmacy in Kentwood, Michigan. The pharmacy operated Monday through Friday from 12:45 am to 4:00 pm, with limited hours on weekends. The pharmacy distributed 220-230 doses each weekday, primarily on one of two runs. The pharmacy's first run began around 2:00 am with deliveries out by 4:00 am. The second run began around 7:00 am with deliveries out by 8:30 am. In addition to unit and bulk doses of technetium-99m, the pharmacy also compounded indium-111 and thallium-201 when necessary, as well as approximately 500-1000 mCi of iodine-131 monthly using an automated capsule fill system. The pharmacy also re-distributed xenon-133 gas vials and iodine-123 capsules without alteration to its clients.

PERFORMANCE OBSERVATIONS

The inspector toured the facility in Kentwood to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent surveys of restricted and unrestricted areas, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The inspector observed a variety of activities on the pharmacy's second run, including molybdenum breakthrough evaluation, dose drawing, client package preparation and vehicle loading, client package return and waste sorting. The licensee's staff also demonstrated the implementation of procedures for generator receipt and use, area surveys, and decay-in-storage waste handling, and discussed with the inspector the only radiological incident since the last inspection, involving a minor needle stick. The inspector had no concerns regarding the licensee's dose assessment or its corrective actions.

The inspector reviewed a selection of records, including daily surveys, weekly air monitoring evaluations and area contamination surveys, dose calibrator quality control documentation, monthly internal audits, annual corporate audits, weekly bioassay results, hazmat training, and dosimetry reports, which indicated maximum exposures in 2016 of 124 mrem whole-body / 8502 mrem extremity, and 35 mrem whole-body / 2515 mrem extremity in 2017 through March 31.

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