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) 2015-001	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	APRIL 21ST 2015

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	4/21/15
BRANCH CHIEF	Aaron McCraw	Robert D. Hatton, Jr. for	4/28/15

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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3. DOCKET NUMBER(S)	4. LICENSE.NUMBER(S)	5. DATE(S) OF INSPECTION
030-34090	21-26707-01MD	April 21, 2015

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 Williams, RPh - RSO	(616) 554-5717

☑ Main Office Inspection Next Inspection Date: 04/21/2017

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of a radiopharmacy in Kentwood, Michigan, which served approximately 20 regular clients in western Michigan. The pharmacy operated Monday through Friday from 12:45 am to 4:00 pm, with limited hours on weekends. The pharmacy distributed 220-245 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 1500 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 in the facility, 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 licensee's second run, including generator elution, molybdenum breakthrough evaluation, kit preparation, dose drawing, client package preparation and vehicle loading, as well as incoming receipt of thallium-201 doses, client package return and waste sorting. The licensee's staff demonstrated the implementation of procedures for dose calibrator quality control, area surveys, I-131 capsule preparation, decay-in-storage waste handling, ventilation hood checks, and spill response.

The inspector also reviewed a selection of licensee records, including daily surveys, weekly air monitoring evaluations, dose calibrator quality control documentation, monthly program assessments by the RSO, annual internal audits, incident reports including dose assessments, weekly bioassay results and monthly film badge reports, which indicated maximum exposures in 2014 of 197 mrem whole-body and 8509 mrem extremity, and 27 mrem whole-body and 1903 mrem extremity in 2015 through February 28th.

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