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
Regional Medical Imaging, P.C. 2486 Nerredia St Flint, MI 48532 REPORT NUMBER(S) 2018001	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
030-31367	21-26076-01	12/20/2018, with in-office review through 1/3/2019

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.

1 Non-cited violation(s) were discussed involving the following requirement(s):

10 CFR 35.63(d) states that unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent. Contrary to this requirement, on April 1, 2016, the licensee administered a 29.7 mCi dosage of technetium-99m (Tc-99m) MDP to a patient who was prescribed 5 mCi of Tc-99m Mebrofenin and was not otherwise directed by an authorized user. The licensee identified the error immediately and determined the root cause of the violation was that multiple doses were measured and ready for injection and the wrong dose was administered. The licensee took corrective actions to only measure and prepare one dose at a time to prevent recurrence.

☐ 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	Jason D. Draper, Health Physicist		1/18/19
BRANCH CHIEF	Aaron T. McCraw		1/18/19

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
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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131	applicable sections of 03.01-03.09

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02200	3	Jill Seorum, NMT Manager	(810) 732-1919

☑ Main Office Inspection Next Inspection Date: 12/20/2021

☑ Field Office Inspection 3346 Lennon Rd, Flint, MI

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced, routine inspection of a nuclear medicine clinic located in Flint, Michigan, authorized to use byproduct material for diagnostic and therapeutic medical purposes. At the time of the inspection, one nuclear medicine technologist performed approximately 5-10 diagnostic administrations each weekday using mostly technetium-99m and occasionally iodine-123, as well as approximately one iodine-131 administration per week for whole body scans or treatment of thyroid conditions. The licensee received unit doses from local radiopharmacies. The licensee retained the services of a medical physics consultant to perform instrument calibrations and to review the content and implementation of the program quarterly.

PERFORMANCE OBSERVATIONS

The inspector toured the licensee's facility in Flint, Michigan (next door to the licensee's mailing address) to evaluate the licensee's measures for material security, exposure control, and postings. The inspector conducted independent surveys throughout the facility and found no evidence of residual contamination nor any exposure rates to members of the public above background in unrestricted areas. The inspector observed the preparation and administration of unit doses for two HIDA scans as well as the receipt of a package containing licensed material. The inspector interviewed the licensee's nuclear medicine technologist regarding the handling and preparation of radiopharmaceuticals, patient release following iodine-131 treatment, and contamination surveys. Through these observations and interviews, the inspector found the licensee's staff to be knowledgeable of radiation protections principles, licensee procedures, and regulatory requirements.

The inspector reviewed the licensee's written directives and release calculations for approximately half of the treatments performed since the last inspection. The inspector also reviewed instrumentation calibration records, survey records, quarterly program audits, and personnel dosimetry reports. During the review of records, the inspector identified one non-cited violation where the licensee identified they had administered a Tc-99m dosage that exceeded the prescribed dosage by more than 20%. The inspector verified this event was not a medical event as defined in 10 CFR 35.3045 and verified the licensee had implemented corrective actions. No other violations of NRC requirements were identified as a result of this inspection.

Draper, Jason

From: Draper, Jason
Sent: Friday, January 18, 2019 12:36 PM
To: 'jseorum@rmipc.net'
Cc: 'rhicks@rmipc.net'
Subject: NRC Form 591M, Regional Medical Imaging, P.C.
Attachments: SKM_C45819011813250.pdf

Ms. Seorum,

As we discussed in our telephone call on Thursday, January 3, 2019, attached is the inspection report for the routine NRC inspection I conducted at your Flint, MI, location on December 20, 2018. Please review and keep this document for your records. There is no response required, though I would appreciate an email confirming that you have received the document. Let me know if you have any questions.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html.

Jason Draper
Health Physicist (Inspector)
NRC/RIII/DNMS/MIB
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