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
Radiopharmacy Incorporated 1409 East Virginia Street Evansville, IN 47711 REPORT NUMBER(S) 16-001	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
030-31910	13-26246-01MD	May 11, 2016

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	5/11/16
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		5/24/16

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	Timothy M. Quinton, R.Ph., RSO	(812) 421-1002

☑ Main Office Inspection Next Inspection Date: 05/11/2018

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine inspection of a radiopharmacy authorized under NRC license to prepare and distribute diagnostic and therapeutic radiopharmaceuticals to clients in the area. The radiopharmacy was staffed with seven authorized nuclear pharmacists (ANPs), three pharmacy technicians, and 15 drivers. Doses were primarily prepared from molybdenum-99/technetium-99m generators. The licensee receives two generators each week and primarily distribute technetium-99 and other radiopharmaceuticals as unit doses. The radiopharmacy's first run began around midnight, with deliveries out by 4:00 AM; the second run began around 6:00 AM and out by 12:00 PM; and additional runs were made as needed through the day. The licensee received and redistributed xenon-133 gas vials, fluorine-18 PET doses, and iodine-125 seeds. The licensee compounded iodine-123 diagnostic and iodine-131 therapy capsules in a ventilated glove box for distribution. The licensee was also authorized to prepare, distribute, and redistribute radium-223, but the licensee has not done any distribution yet.

Performance Observations:

The inspection consisted of interviews with select licensee personnel; review of select records; tour of the facility; and independent measurements. 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, DOT package labeling and vehicle loading, as well as client package return and waste handling. The licensee's staff also demonstrated the implementation of procedures for area surveys, I-131 capsule preparation, ventilation hood air monitoring and filter change out procedures, and decay-in-storage waste handling, with no issues noted. Interviews with licensee staff and through demonstrations indicated the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements. The inspector observed personnel monitoring themselves for contamination at each exit of the restricted area. The inspector reviewed the molybdenum breakthrough check records, dose calibrator quality control, I-131 release evaluations, daily restricted area and weekly unrestricted area surveys, decay-in-storage waste disposals, hazmat training, quarterly program audits, sealed source inventory, and leak test reports, with no findings. The inspector reviewed dosimetry records for 2014 and 2015, indicating the maximum annual dose to be 131 mrem whole-body and 14,939 mrem extremity, and performed independent and confirmatory radiation measurements which indicated results consistent with the licensee's survey results and within regulatory limits.

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