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, Indiana REPORT NUMBER(S) 2014-001	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
030-31910	13-26246-01MD	3/25&28/14, with in-office review through 4/1/14

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.	4/15/14
BRANCH CHIEF	Aaron T. McCraw		4/15/14

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 through 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	Tim Quinton, RSO	(812) 421-1002

☑ Main Office Inspection Next Inspection Date: 03/25/2016

☐ Field Office Inspection

☑ Temporary Job Site Inspection Deaconess Hospital in Evansville, Indiana

PROGRAM SCOPE

The in-office review included receipt and review of information that was unavailable during the onsite inspection regarding compliance with the constraint on air emissions (10 CFR 20.1101(d)). The licensee prepared and delivered diagnostic and therapeutic radiopharmaceuticals to clients in the area. The licensee had five authorized nuclear pharmacists (ANPs). Iodine-131 compounding was periodically conducted; however, it was not done during the onsite inspection.

Performance Observations

Incident to conducting an inspection at Deaconess Hospital, the inspector observed a driver deliver licensed material. The inspector observed the driver demonstrate how he: (1) blocked and braced packages for transport; (2) would respond to a transportation accident based on a scenario posed by the inspector; and (3) stowed shipping papers in the vehicle. The inspector noted that the driver donned his dosimeter badge. At the licensee's facility, the inspector observed: (1) that licensed material was secured as required; (2) an ANP conduct a molybdenum-99 breakthrough test on each elution; (3) an ANP demonstrate how he would identify a failed molybdenum-99 breakthrough test and respond to it; (4) staff don whole body and extremity dosimeters in the radiopharmacy; (5) staff don protective clothing and use time, distance and shielding to reduce radiation doses; (6) that the licensee did not receive its first shipment of radium-223 chloride because its license amendment request to do so was not approved; (7) an ANP elute a technetium-99 generator; (8) that a radiopharmaceutical was heated within an enclosure to achieve containment in the event of vial breakage; (9) staff prepare packages for delivery; (10) that selected shipping papers contained required information; (11) staff conduct package radiation surveys prior to shipment; (12) that selected survey instruments were calibrated as required; (13) an ANP demonstrate how he had conducted iodine-131 compounding; (14) an ANP demonstrate how had conducted fume hood face velocity measurements and filter changes; (15) that the highest annual whole body and extremity doses received in 2012 through January 31, 2014, were 140 millirem and 22055 millirem, respectively; (16) selected records that showed the licensee complied with 10 CFR 20.1101(d); (17) personnel monitoring themselves for contamination at each exit of the restricted area; (18) records of the licensee's program audits; (19) records of dose calibrator calibration tests; (20) sealed source inventory records; and (21) selected leak test records.