NRC FORM 591M PART 1
(10-2011)
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) 12-01	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	August 22, 2012

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 P. Hays	Robert P. Hays	8/22/12
BRANCH CHIEF	Tamara E. Bloomer	for	8/31/12

NRC FORM 591M PART 3
(10-2011)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
IP 87125	03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2500	2	Tim Quinton, RSO	(812) 421-1002

☑ Main Office Inspection Next Inspection Date: 08/22/2014

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This nuclear pharmacy staff included 4 pharmacists, 5 pharmacy technicians, and 14 drivers. The licensee receives two generators each week and prepares and distributes an average of 250 unit doses per week day. In addition to unit doses, the pharmacy distributes xenon-133 gas vials, iodine-123, therapeutic beta emitters, compounded I-131 capsules as ordered, blood labeling, and F-18.

Performance Observations

Interviews with licensee personnel indicated an adequate knowledge of radiation safety concepts and procedures provided through recurring training. The inspector observed unit dose preparation and procedures in progress and the licensee's staff demonstrated/discussed: (1) unit dose prep and safe use procedures; (2) iodine compounding procedures; (3) package returns and breakdown procedures; (4) area and contamination surveys; (5) DOT packaging and transportation procedures; (6) unit dose management system (bar coding); (7) F-18 procedures; (8) wipe test counting and efficiency procedures; (9) survey instruments and calibrations; (10) postings and labeling; (11) staff training; (12) quarterly and annual radiation safety program audits; (13) thyroid bioassays; (14) waste handling; (15) facility security (staff observed inspector arrive at facility and questioned about being on site before inspector identified himself); (16) dose calibrator tests; (17) sealed source inventories and leak tests; (18) weekly iodine effluent monitoring (< 20% of constraint limits); (19) any events involving licensed material; and (20) the highest cumulative weekly and monthly dosimetry records indicated:

2010: 351 mrem DDE (whole body); and 16055 mrem SDE (extremity).
2011: 205 mrem DDE (whole body); and 15305 mrem SDE (extremity)
2012: 49 mrem DDE (whole body); and 9213 mrem SDE (extremity) through 6/30/2012

The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

ATM