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
Indiana University Health Arnett Hospital 5165 McCarty Lane Lafayette, IN 47905 REPORT NUMBER(S) 13-01	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
030-37189	13-32535-02	August 15, 2013

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	Claire E. Wellinghoff	Claire Wellinghoff	8/22/13
BRANCH CHIEF	Aaron McCraw		8/23/13

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
87131	3.01-3.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2200	3	Rodney Dunseath, D.O., RSO	(765) 448-8122

☑ Main Office Inspection Next Inspection Date: August 16, 2014

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

The licensee was a medical institution with authorization for materials in Sections 35.100, 35.200, and 35.300. The nuclear medicine department was staffed with one full-time, and 3 part-time nuclear medicine technologists (NMT) who performed close to 15 diagnostic nuclear medicine procedures per day. Additionally, the licensee performed approximately 2 therapeutic I-131 procedures per day; all patients treated with I-131 were released under the provisions of Section 35.75. The studies included a full spectrum of diagnostic imaging studies (primarily cardiac rest and stress tests) with doses ordered from a local radiopharmacy. The licensee primarily used unit doses, but would order roughly 100 mCi of bulk (per week) in the event that a patient required additional dosages for a diagnostic test. The licensee employed an outside health physics consultant to audit the radiation safety program on a quarterly basis.

Performance Observations

During the time of the inspection, the inspector observed one patient administration. The inspector observed an NMT: (1) assay the dose; (2) carry the dose in a shielded box to the patient injection area; (3) administer the dose; and (5) properly dispose of waste after use. The NMTs demonstrated package receipt procedures, daily calibrator checks, daily surveys, security of byproduct material, and spill response procedures with no issues identified. The inspection also consisted of a review of select licensee records including: (1) linearity test records; (2) weekly wipe test results; (3) quarterly audit reports; (4) Radiation Safety Committee (RSC) meeting minutes (last on 6/14/13 with no findings); (5) leak test records; (6) inventory records; and (7) written directives. The written directives contained appropriate information including the patient name, prescribed dose, administered dose, and had been signed and dated by an appropriate Authorized User. Of the written directives reviewed, the inspector observed several administered doses over 100 mCi of I-131. Additionally, independent measurements were taken in the hot lab with no reading observed above background levels.

Note to next inspector: On August 16, 2013, the licensee was approved for authorization of material under Section 35.1000. In accordance with Manual Chapter 2800, due to the significant expansion of the program, the licensee shall be inspected within 12 months of the date of the amendment.