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) 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
030-37189	13-32535-02	April 5, 2018

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	Dennis P. O'Dowd	Dennis P. O'Dowd	04/05/18
BRANCH CHIEF	Aaron T. McCraw		4/20/18

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
87130, 87131, & 87132	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	2	Joshua A. Nepute, M.D., RSO	(765) 448-8122

☑ Main Office Inspection Next Inspection Date: 04/05/2018

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced, routine inspection of a large community hospital (260 beds) authorized to use byproduct material authorized in Sections 35.100, 35.200, 35.300, and Y-90 microspheres in the SIR Spheres brachytherapy delivery system. The licensee staffed its nuclear medicine department with three FT nuclear medicine technologists who performed studies daily; there were six trained cardiac nurses who routinely administered cardiac stress doses. The department administered approximately 200-250 patient studies per month which included a full spectrum of studies (excluding Xe-133). The licensee received its material in unit and bulk (100 mCi) doses daily from a licensed radiopharmacy. The licensee administered 80-90 I-131 cases annually; the licensee obtained its radioiodine in capsule form. The licensee administered one Ra-223 Xofigo treatment in early 2017, with no further uses to date. The licensee administered 6 SIR Spheres treatments in 2016, 7 cases in 2017, and 5 cases YTD 2018. The hospital retained the services of a consultant who performed quarterly audits of the radiation safety program. The licensee maintained a radiation safety committee that met on a quarterly basis.

PERFORMANCE OBSERVATIONS

The inspector toured the nuclear medicine department and adjacent cardiac treadmill room, to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector observed the preparation and administration of several cardiac studies, package receipt, instrument quality control and waste handling by nuclear medicine staff. Licensee personnel demonstrated nuclear medicine daily checks, and daily/weekly area surveys, and described planning and administration of therapeutic procedures. No therapeutic procedures were conducted by the licensee at the time of the inspection. The inspector reviewed the licensee's procedures for Y-90 SIR Spheres administrations, and licensee staff demonstrated the implementation of licensee procedures for Sir-Sphere treatment planning and administration. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings. The inspector reviewed a selection of written directives and treatment plans for I-131, Ra-223, and Y-90 uses since the last inspection, routine nuclear medicine records, training records, dosimetry reports, consultant audits, and RSC meeting minutes. Review of dosimetry records indicated no exposures of regulatory concern.

No violations of NRC requirements were identified during this inspection.