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) 14-01	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	March 24, 2014

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	Andrew M. Bramnik	Andrew M Bramnik	3/24/14
BRANCH CHIEF	Aaron T. McCraw		4/4/14

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
87132	03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	2	Rodney A. Dunseath, RSO	(765) 448-8122

☑ Main Office Inspection Next Inspection Date: 03/24/2016

☑ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

The licensee was a small hospital with authorization for activities under 10 CFR 35.100, .200, and .300. On August 16, 2013, the license was amended to add yttrium-90 Sir-Spheres under 10 CFR 35.1000. This inspection focused on the Y-90 program in accordance with Inspection Manual Chapter 2800. At the time of the inspection, the licensee had conducted a total of four Y-90 treatments for two patients: each patient had been separately treated for the left and right sides of their liver. The inspection consisted of interviews with licensee personnel, demonstrations of selected activities, and a review of selected records. The licensee also added a second location of use for diagnostic imaging in August 2013; however, the licensee's plans to acquire a camera for the new location fell through, and they had not used or stored any radioactive material at the new location. The licensee was evaluating whether to remove the second location of use from their license at the time of the inspection.

PERFORMANCE OBSERVATIONS

The licensee demonstrated how Y-90 vials were received in the hospital's nuclear medicine department, which was staffed with four nuclear medicine technologists (NMTs). The technologists demonstrated how packages containing Y-90 were received, surveyed, documented, and stored. The licensee's survey meter and other instrumentation were appropriately calibrated and verified to be operational. One of the licensee's authorized users (AUs) described how the patients were consulted, evaluated for treatment with Sir-Spheres, and tested to assess potential lung shunting. The licensee surgically removed the gastroduodenal artery from all Y-90 patients in order to prevent radioactive material from being transported to the gastrointestinal tract.

The inspector reviewed the licensee's records of all four procedures performed to-date. For each treatment, the licensee completed a written directive that was consistent with their license commitments and signed by an AU prior to the treatment. The licensee's AU and another oncologist described pre-treatment "time out" discussions to help provide high confidence that each treatment was in accordance with the written directive. The NMTs described how they measured Y-90 activity in each vial before and after treatments in order to determine how much material was delivered to the patient. An NMT conducted contamination surveys for all personnel present during Y-90 treatment administrations. An NMT also completed a worksheet of assays and results before and after each administration in accordance with the manufacturer's instructions. The licensee described their process in case stasis was reached prior to the conclusion of the treatment; however, at the time of the inspection that had not occurred at the licensee's facility.