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 Goshen Hospital Department of Nuclear Medicine 200 High Park Avenue Goshen, Indiana 46526 REPORT NUMBER(S) 2013001	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
030-14254	13-18845-01	January 23 , 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	Geoffrey M. Warren		1/23/13
BRANCH CHIEF	Tamara E. Bloomer		2/7/13

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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030-14254	13-18845-01	January 22 - 23, 2013

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131, 87132	03.01 - 03.08; 03.01 - 03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	2	John Lowden, MS, RSO	(574) 634-2538

☑ Main Office Inspection Next Inspection Date: Jan. 2015

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

The licensee was a 120-bed hospital facility located in Goshen, Indiana, with authorization to use byproduct materials in Sections 35.100, 35.200, and 35.300, as well as yttrium-90 as microspheres and iridium-192 in a high dose rate (HDR) remote afterloader. While authorized to perform brachytherapy procedures under 35.400, the licensee had not performed any such procedures in several years and had no plans to reactivate the program.

The nuclear medicine department was staffed with four full-time nuclear medicine technologists, who typically administered 200 diagnostic doses monthly, including the full spectrum of procedures using technetium-99m, indium-111, xenon-133, and other isotopes. Therapy procedures included 14 iodine-131 procedures using capsules annually, including whole body scans and hyperthyroid treatments, and five samarium-153 procedures annually. Doses were received as unit doses or prepared from bulk technetium. The licensee's PET area was staffed with two technologists who performed 70 procedures monthly, including tumor, brain, and bone imaging using fluorine-18.

The radiation therapy department was staffed with two physician authorized users, two medical physicists, and several therapists who assisted during procedures. The radiation therapy staff performed approximately 25 HDR fractions (four patients) monthly and six microspheres treatments annually. HDR procedures included breast, gynecological, prostate, bronchial, and other procedures.

Performance Observations: The inspector observed three diagnostic administrations of licensed materials, including dose preparation and disposal. Licensee personnel demonstrated morning checks for HDR and nuclear medicine, and daily and weekly contamination surveys, and described preparation and administration of therapeutic and diagnostic radiopharmaceuticals, planning and performance of HDR and microspheres treatments, and emergency procedures. The inspector noted no concerns with these activities. The inspector reviewed written directives for radiopharmaceutical therapies, HDR treatments, and microspheres procedures, and identified no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Dosimetry records indicated no exposures of regulatory concern. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings. Review of radiation safety committee minutes showed good attendance and discussion of appropriate topics.