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
Memorial Hospital 615 North Michigan Street South Bend, Indiana 46601 REPORT NUMBER(S) 2016-001	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
030-17335	13-18881-01	June 22-23, 2016

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		6/23/16
BRANCH CHIEF	Aaron T. McCraw		6/30/16

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, 87132	03.01 - 03.09, 03.01 - 03.09

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	2	Daniel J. Archambeault, M.S., RSO	(574) 647-7956

☑ Main Office Inspection Next Inspection Date: June 22, 2018

☑ Field Office Inspection 610 North Michigan St, South Bend IN

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced, inspection. The licensee was a 436-bed hospital located in South Bend, Indiana, with authorization to use byproduct materials in Sections 35.100, 35.200, 35.300, and 35.400, as well as iridium-192 in a high dose rate (HDR) remote afterloader unit and yttrium-90 as microspheres. The licensee had performed no microspheres procedures since before the previous inspection. Licensed activities were conducted only at the facilities identified on the license. The main nuclear medicine department was staffed with five to six full-time nuclear medicine technologists. The technologists typically administered 300 diagnostic doses monthly, 20 iodine-131 therapy doses quarterly, and occasional radium-223 chloride therapy procedures. The diagnostic procedures included a wide variety of imaging and uptake studies, with doses received as unit doses or prepared from bulk techetium-99m. Iodine-131 doses were received as capsules. All doses were received from a licensed nuclear pharmacy. At the 610 N. Michigan St. facility, a cardiology clinic, one to two technologists performed 200 cardiology stress tests monthly using unit doses. The RSO stated that the Mishawaka facility included a PET imaging clinic.

The radiation oncology department at the main hospital was staffed with two physician authorized users, one medical physicist, and several therapists who assisted during procedures. The radiation oncology staff performed approximately ten HDR fractions monthly, primarily prostate and gynecological procedures; and two permanent prostate implant procedures annually using iodine-125 and cesium-131 seeds.

Performance Observations: The inspector observed five diagnostic administrations of licensed material, including dose preparation and disposal. Licensee personnel demonstrated morning checks in nuclear medicine, package receipt surveys and wipes, daily checks for HDR, and daily and weekly contamination surveys, and described procedures for a variety of diagnostic and therapeutic administrations of licensed materials. The inspector noted no concerns with these activities. The inspector reviewed written directives for radiopharmaceutical therapies, HDR treatments, and brachytherapy procedures, and identified no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry records indicated no exposures of regulatory concern. Radiation safety committee minutes showed good attendance and discussion of appropriate topics. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings. No violations were identified during this inspection.