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 N. Michigan Street South Bend, Indiana REPORT NUMBER(S) 12-001 & 12-002	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	9/4-6/12

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)

10 CFR 35.41(a) states that, for any adminstration requuiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

Contrary to the above, from approximately July 1, 2009, until September 6, 2012, the licensee did not develop written procedures to provide high confidence that each high dose rate remote afterloader treatment administration is in accordance with the written directive.

As corrective action, the licensee committed to revise its applicable procedures by 9/23/12 to add verification

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	Daniel J. Archambeault	Daniel J. Archambeault	9/21/12
NRC INSPECTOR	Robert G. Gattone, Jr.	Robert G. Gattone, Jr.	9/20/12
BRANCH CHIEF	Tamara E. Bloomer	for	9/21/12

NRC FORM 591M PART 2
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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Memorial Hospital 615 N. Michigan Street South Bend, Indiana REPORT NUMBER(S) 12-001 & 12-002	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

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(Continued)

that the number of fractions per week are as per the written directive/treatment plan prior to each administration.

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131, 87132	1-9, 1-9

SUPPLEMENTAL INSPECTION INFORMATION

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

☑ Main Office Inspection Next Inspection Date: 09/06/2014

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

Medical use was conducted under the supervision of physician authorized users. No therapeutic administrations occurred during the inspection. The licensee used an authorized HDR remote afterloader device for gynecological treatments about 3 times per year, prostate treatments about 3 times per year, and breast treatments about 12 times per year. The licensee used I-125, Pd-103, and Cs-131 to treat prostate glands about 12 times per year. SirSpheres were administered about twice per year. Seven full time and 2 part time nuclear medicine technologists (NMT) worked from 7:00 am to 4:00 pm Monday through Friday and conducted the full spectrum of diagnostic studies (about 15 per day, unit dosages only from Cardinal Health in South Bend). About two I-131 hyperthyroid treatments were done per week and about two I-131 thyroid cancer treatments were done per month. At the 610 N. Michigan facility, one or two NMTs conducted cardiac diagnostic studies exclusively from 7:00 am to 4:00 pm Monday through Friday. The inspector identified a violation of 10 CFR 35.41 (see Part 1). Specifically, the licensee's procedure was silent regarding verification that, prior to administration, the number of fractions per week were in accordance with the written directive (Note: The number of fractions per week was part of the written directive for some treatments). The inspector identified that an HDR treatment administered based on a written directive dated 6/14/12 resulted in administration of 2 fractions in a week; however, the written directive stated that 1 fraction be administered per week.

Performance Observations

The inspector observed: (1) that licensed material was secured; (2) applicable records and interviewed applicable staff to understand how HDR, radiopharmaceutical, low dose rate brachytherapy, and SirSphere treatments were conducted; (3) the AMP demonstrate how HDR spot checks were done; (4) that selected licensee survey instruments were calibrated; (5) expected results while conducting confirmatory and independent surveys with an NRC-owned Ludlum Model 2403 instrument that was calibrated on 5/14/12; (6) a radiation therapist demonstrate how she would respond to an HDR source stuck in an unshielded position based on scenarios posed by the inspector; (7) that no food or drink was in the hot lab; (8) records that a patient received 224 microcuries of Tc-99m-labeled sulfur colloid intradermally on the wrong side for unilateral sentinel node scintigraphy in January 2010, and no medical event resulted because the skin received less than 8 rem and the whole body received less than 5 rem; (9) selected NMTs prepare and administer diagnostic radiopharmaceuticals; (10) staff don appropriate PPE and dosimetry badges; (11) that an NMT identified a minor spill during a diagnostic administration, decontaminated the patient and the area, and surveyed as necessary to confirm that the area was decontaminated; and (12) that dosimetry badge readings were well below the dose limits.