NRC FORM 591M PART 1
(10-2003) 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, IN 46601** **REPORT NUMBER(S)** **2010-01**	**U.S. Nuclear Regulatory Commission** **Region III** **2443 Warrenville Road** **Suite 210** **Lisle, Illinois 60532-4351**

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-17335	**13-18881-01**	May 20 & 21, 2010

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 violation(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, NUREG-1600, to exercise discretion, were satisfied.

_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Licensee's Statement of Corrective Actions for Item 4, above.

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	**Robert P. Hays**		5/21/10

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NRC FORM 591M PART 3
(10-2003) 10 CFR 2.201

Docket File Information

U.S. NUCLEAR REGULATORY COMMISSION

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1. LICENSEE	2. NRC/REGIONAL OFFICE
Memorial Hospital REPORT NUMBER(S) **2010-01**	**Region III** **2443 Warrenville Road, Suite 210** **Lisle, IL 60532**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
03017335	**13-18881-01**	**May 20 -21, 2010**

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87124 (11/25/03)	**03.01-03.07**

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	**2**	**D. Archambeault, RSO**	**574-647-7556**

[X] Main Office Inspection — Next Inspection Date: **May 2012**

[X] Field Office **610 North Michigan Street, Suite 400, South Bend, Indiana**

[ ] Temporary Job Site Inspection

PROGRAM SCOPE

The licensee was a medical institution located in South Bend, Indiana, with authorization by the license for diagnostic and therapeutic nuclear medicine procedures, low dose brachytherapy procedures, Y-90 microspheres procedures and a GammaMed remote afterloading brachytherapy device. Since the previous inspection, the licensee has added one additional location of use on their license at 610 North Michigan Avenue, Suite 400, South Bend, Indiana, and under the name of Memorial Advanced Cardiology Institute. Currently, this licensee facility conducts 2 to 3 nuclear cardiology studies only on Fridays each week, using a mobile medical service, until the licensee receives all equipment necessary to conduct nuclear cardiology studies "in house". Also since the previous inspection, the license has been amended to add the use of SIR-Spheres (Y-90) for treatment of liver cancer and has treated 10 patients with this modality. The licensee also uses a GammaMed HDR unit for MammoSite therapy and has treated 200 patients within the previous year. The current inspection effort focused on the recent addition of the additional authorized location of use, SIR-Spheres, and routine use of the HDR. The HDR staff included two medical physicists who perform treatment setup and double checks of the treatment plan. Source exchanges are performed four times per year.

Performance Observations

During the inspection, the licensee's available staff demonstrated/discussed: (1) survey instruments and required surveys; (2) package receipt and check-in procedures; (3) dosimetry (< 10% of annual regulatory limits); (4) written directives and treatment plans; (5) security and storage of licensed material; (6) electrometer and well-chamber instrument calibrations; (7) GammaMed calibrations and output checks; (8) GammaMed daily checks; (9) emergency tools and procedures; (10) acceptance testing; (11) HDR annual refresher training/emergencydrills; (12) radiation safety program audit results; (13) SIR-Sphere procedures; and (14) quarterly radiation safety committee meetings. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.