

NRC FORM 591M PART 1 (4-2008) 10 CFR 2.201		U.S. NUCLEAR REGULATORY COMMISSION	
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION			
1. LICENSEE/LOCATION INSPECTED: St. Mary's Medical Center See Part 3 of this report for locations inspected		2. NRC/REGIONAL OFFICE REGION III US NUCLEAR REGULATORY COMMISSION 801 WARRENVILLE ROAD LISLE IL 60532-4351	
REPORT NUMBER(S) 2008-001			
3. DOCKET NUMBER(S) 03020812		4. LICENSE NUMBER(S) 13-03226-04	5. DATE(S) OF INSPECTION 8/26-29/08
<p>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:</p> <p><input type="checkbox"/> 1. Based on the inspection findings, no violations were identified.</p> <p><input type="checkbox"/> 2. Previous violation(s) closed.</p> <p><input type="checkbox"/> 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.</p> <p style="padding-left: 40px;">non-cited violation(s) were discussed involving the following requirement(s):</p>			
<p><input checked="" type="checkbox"/> 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.</p> <p>(Violations and Corrective Actions)</p> <p>Title 10 CFR 35.40(b)(5) requires, in part, that the written directive for high dose rate remote afterloading brachytherapy (HDR) include: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose. Contrary to the requirement, two licensee HDR written directives each dated July 7, 2008, did not include the total dose, and a licensee HDR written directive dated July 8, 2008, did not include the radionuclide. As corrective action, the licensee committed to revise its HDR written directive form to include the total dose and specify the radionuclide as, "iridium-192" before the next HDR treatment.</p>			
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	SAIYID M. SHAH, PH.D.	<i>S. M. Shah</i>	9-8-08
NRC INSPECTOR	Robert G. Gattone, Jr.	<i>Robert G. Gattone, Jr.</i>	9/3/08 ✓

for

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(Continued)

Title 10 CFR 35.14(b)(4) requires that the licensee notify the NRC no later than 30 days after it has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with 10 CFR 35.100 or 35.200. Contrary to the requirement, in January 2007, the licensee added areas of use where byproduct material was used in accordance with 10 CFR 35.100 or 35.200 (i.e., P.E.T. activities) and, as of August 28, 2008, the licensee had not notified the NRC. As corrective action, the licensee committed to: (1) notify the NRC of the change by September 5, 2008; (2) add verification of compliance with the requirement as an agenda item for Radiation Safety Committee meetings; and (3) designate a manager to ensure future compliance with the requirement.

Title 10 CFR 35.643(b) requires, in part, that the licensee perform spot checks for remote afterloader units in accordance with written procedures established by the authorized medical physicist. Contrary to the requirement, as of September 3, 2008, the licensee's authorized medical physicist had not established written procedures for performing spot checks for remote afterloader units. As corrective action, the licensee committed to have its authorized medical physicist establish written procedures for performing spot checks for remote afterloader units within 30 days.

Docket File Information
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6. INSPECTION PROCEDURES USED 87131, 87132, and 87122		7. INSPECTION FOCUS AREAS 03.01-03.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02230	2. PRIORITY 2	3. LICENSEE CONTACT Saiyid Shah, RSO	4. TELEPHONE NUMBER 812-473-1110
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Main Office Inspection Next Inspection Date: 08/29/2010

Field Office Inspection See below

Temporary Job Site Inspection _____

PROGRAM SCOPE

The inspection was conducted at the following Evansville, IN facilities: 3801 Bellemeade Avenue, 3700 Washington Avenue, and 901 St. Mary's Drive.

The licensee treated about two patients per month with an authorized HDR unit. Most HDR treatments were Mammosite, some were gynecological. No HDR treatments were conducted during the inspection. The licensee conducted the full spectrum of nuclear medicine procedures, including therapies with iodine-131. The licensee used unit dosages of flourine-18 FDG to conduct P.E.T. The licensee used an authorized, self-shielded irradiator to irradiate cellular products about 25 times per month.

PERFORMANCE OBSERVATIONS

The inspector observed: (1) staff secure licensed material as required; (2) that the licensee had posted the facilities as required; (3) a dosimetrist demonstrate how procedures for administrations requiring a written directive for HDR were implemented; (4) a dosimetrist demonstrate how HDR spot checks were done; (5) a dosimetrist demonstrate response to an HDR source stuck in the unshielded position based on a scenario posed by the inspector; (6) selected nuclear medicine technologists (NMTs) prepare and administer diagnostic dosages; (7) an NMT demonstrate how packages of spent dosages were prepared for return to a nuclear pharmacy; (8) an NMT demonstrate how packages of licensed material were received from a nuclear pharmacy; (9) an NMT prepare and administer an iodine-131 dosage to a patient; (10) an NMT demonstrate response to a patient vomiting after administration of iodine-131 based on a scenario posed by the inspector; (11) an NMT demonstrate how procedures for administrations requiring a written directive for nuclear medicine were implemented; (12) an NMT prepare and administer a flourine-18 FDG dosage to a patient; (13) an NMT demonstrate how survey instrument operability checks were conducted; (14) a medical technologist demonstrate how the irradiator was used; (15) a medical technologist demonstrate response to a fire involving the irradiator based on a scenario posed by the inspector; (16) a biomedical technician demonstrate how leak test samples were obtained from the irradiator; and (17) the licensee conduct a Radiation Safety Committee meeting.