

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

**St. Mary's Health Center
6420 Clayton Road
St. Louis, MO 63117**

2. NRC/REGIONAL OFFICE

**U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4351**

REPORT NUMBER(S) **2011-01**

3. DOCKET NUMBER(S)
030-02351

4. LICENSEE NUMBER(S)
24-08960-02

5. DATE(S) OF INSPECTION
August 11, 2011

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:

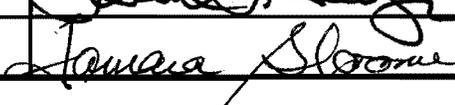
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied

_____ Non-cited violation(s) 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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11

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	Robert P. Hays		8/11/11
Branch Chief	Tamara E. Bloomer		8/18/11

NRC FORM 591 M PART 3 (06-2010) 10 CFR 2.201		U.S. NUCLEAR REGULATORY COMMISSION	
<i>Docket File Information</i> SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION			
1. LICENSEE St. Mary's Health Center 6420 Clayton Road St. Louis, MO 63117 REPORT NUMBER(S) 2011-01		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4351	
3. DOCKET NUMBER(S) 03002351	4. LICENSE NUMBER(S) 24-08960-02	5. DATE(S) OF INSPECTION August 11, 2011	
6. INSPECTION PROCEDURES 87131 (10/24/02)	7. INSPECTION FOCUS AREAS 03.01-03.07		
SUPPLEMENTAL INSPECTION INFORMATION			
1. PROGRAM 2230	2. PRIORITY 2	3. LICENSEE CONTACT Greg Wunsch, Chief NMT	4. TELEPHONE NUMBER 314-205-6218
<input checked="" type="checkbox"/> Main Office Inspection		Next Inspection Date: <u>August 2013</u>	
<input type="checkbox"/> Field Office Inspection			
<input type="checkbox"/> Temporary Job Site Inspection _____			
PROGRAM SCOPE			
<p>The licensee was a medical institution with authorization by the license to use byproduct materials for diagnostic and therapeutic medical procedures under 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.600 using a Nucletron microSelectron Model 106.990.</p> <p>The nuclear medicine department was staffed with three nuclear medicine technologists (NMTs). The NMTs administered a daily average of 10-15 diagnostic studies, with the majority being cardiac studies using myoview or thallium as ordered by the authorized user. Iodine-123 is administered for uptake studies and averaged 1-2 cases per week. Xe-133 was occasionally administered for lung studies. Iodine-131 dosages requiring a written directive were for hyperthyroid therapies only and averaged 4-5 administrations per year. Sm-153 therapy administrations averaged one patient per year. The nuclear medicine department received unit doses from two St. Louis nuclear pharmacies. All waste was either held for decay-in-storage (DIS) or returned to the nuclear pharmacy as limited quantity shipments.</p>			
<u>Performance Observations</u>			
<p>During the inspection, the licensee's NMT staff demonstrated/discussed: (1) survey instruments and required surveys; (2) package receipt and check-in procedures; (3) wipe test counting; (4) unit dose and safe handling procedures; (5) I-131 procedures, written directives, and 10 CFR 35.75 requirements; (6) waste handling; (7) sealed source inventories and leak tests; (8) security and storage of licensed material; (9) Sm-153 calibration procedures (10) quarterly radiation safety program audit results; (11) dosimetry: [CY 2009: 308mr-DDE; 540mr-SDE], [CY 2010 215mr-DDE; 560mr-SDE], and [YTD through June 2011: 122mr DDE, 270 mr SDE]. The inspector performed independent and confirmatory radiation measurements, which indicated results consistent with licensee survey records and postings.</p>			
Continued on next page			

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<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <input checked="" type="checkbox"/> Main Office Inspection <input type="checkbox"/> Field Office Inspection <input type="checkbox"/> Temporary Job Site Inspection _____ </td> <td style="width: 50%; vertical-align: top; padding-left: 20px;"> Next Inspection Date: <u>August 2013</u> </td> </tr> </table>				<input checked="" type="checkbox"/> Main Office Inspection <input type="checkbox"/> Field Office Inspection <input type="checkbox"/> Temporary Job Site Inspection _____	Next Inspection Date: <u>August 2013</u>
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PROGRAM SCOPE					
<p>The licensee is authorized for low dose brachytherapy procedures, however, no 10 CFR 35.400 procedures have been performed since 2009.</p> <p>The Oncology Department used a Nucletron HDR afterloader for occasional MammoSite and routine cervical cancer therapies and averaged 1-2 patient cases per month. The licensee's Oncology Department was staffed with one primary authorized user, one medical physicist, and one dosimetrist, who perform treatment setup and double checks of the treatment plan. Source exchanges are performed on a quarterly frequency.</p> <p style="text-align: center;"><u>Performance Observations</u></p> <p>During the inspection, the licensee's medical physicist demonstrated/discussed: (1) survey instruments, required surveys, and calibrations; (2) package receipt and check-in procedures; (3) written directives and treatment plans; (4) security and storage of licensed material; (5) electrometer and well-chamber instrument calibrations; (6) quarterly full calibrations and output checks; (7) daily checks; (8) emergency tools and posted procedures; (9) PrimeAlert radiation monitor testing and battery backup; (10) HDR annual refresher training and emergency drills; and (11) written procedures. The inspector performed independent and confirmatory radiation measurements, which indicated results consistent with licensee survey records and postings.</p>					