Inspection Record

Region: **III**
Inspection Report No. **03010108/2011-01(DNMS)**

License No. **24-01041-04**
Docket No. **030-10108**

Licensee:
St. Anthony's Medical Center
10010 Kennerly Road
St. Louis, MO 63128

Location Being Inspected: **10010 Kennerly Road, St. Louis, MO**
12700 Southfork Road, St. Louis, MO

Licensee Contact: **David J. Keys, Ph.D., Radiation Safety Officer**
Telephone No.: **(314) 525-4064; dkeys@med-phys.com**

Priority: **2** Program Code: **2230**

Date of Last Inspection: **January 15, 2009** Date of This Inspection: **January 26, 2011**

Type of Inspection: ( ) Initial ( ) Announced (**X**) Unannounced
(**X**) Routine ( ) Special

Next Inspection Date: **January 2013** (**X**) Normal ( ) Reduced

Justification for reducing the routine inspection interval: **N/A**

Summary of Findings and Actions:

( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
(X) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector(s): **Robert P. Hays** Date 2/22/11
(Signature)

Approved: **Tamara E.. Bloomer** Date 2/22/11
(Signature)

Enclosure

PART I - LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

AMENDMENT #	DATE	SUBJECT
50	**November 10, 2010**	**Amend license for Oncura seeds**

2. INSPECTION AND ENFORCEMENT HISTORY:

The previous inspection on July 28 and 29, 2008, identified a SL III violation for a failure to secure licensed material. No violations were identified during the six-month follow up inspection conducted on January 15, 2009, for corrective actions after escalated enforcement regarding the unsecured licensed material.

No violations were identified during a prior inspection conducted on 1/19/2006.

3. INCIDENT/EVENT HISTORY:

None

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Brian Pence, Director of St. Anthony's Cancer Center
David Keys, Ph.D., RSO and Medical Physicist

The licensee was a medical institution located in St. Louis, Missouri, with authorization by the license for diagnostic and therapeutic nuclear medicine procedures, low dose brachytherapy procedures, and two GammaMed high dose-rate remote (HDR) afterloading brachytherapy devices. Therapy treatments using the GammaMed HDR average two patients per month and prostate implants also averaged two patient cases per month. The current inspection effort focused on routine use of the HDR, prostate seed implants, and follow-up for a licensee self-identified violation pertaining to receiving two shipments of Oncura Model 6711 iodine-125 seeds without St. Anthony's being authorized by its NRC license to receive the seeds. The HDR staff included two medical physicists who perform treatment setup and double checks of the treatment plan. Source exchanges are performed three times per year.

The licensee has one additional location of use on their license at 12700 Kennerly Road, St. Louis, MO, authorized for sentinel lymph node (SLN) biopsy procedures. The inspection determined that no procedures involving licensed material have been conducted since the previous inspection.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: **87124**

Focus Areas Evaluated: **03.01-03.07**

The records reviewed included records since the previous inspection and included: (1) survey instrument calibrations; (2) package receipt records; (3) dosimetry (< 10% of annual regulatory limits); (4) HDR and seed written directives and treatment plans; (5) electrometer and well-chamber instrument calibrations; (6) GammaMed calibrations and output checks; (7) GammaMed daily checks; (8) acceptance testing; (9) HDR annual refresher training and emergency drills; (10) seed implant procedures and D90 dose; (11) radiation safety program audit results; (12) quarterly radiation safety committee meetings; and (13) SLN biopsy records pertaining to use of licensed material at 12700 Southfork Road.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector performed independent radiation measurements of the HDR device and ambient surveys of the source storage room, which indicated no unusual dose rate concerns and were consistent with expected survey results for the type of device.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

On November 9, 2010, the licensee's RSO notified NRC that they had received two shipments of iodine-125 seeds, Oncura Model 6711, not authorized by St. Anthony's license. The licensee identified the issue during a routine audit of its licensed activities by the RSO. Normally, the receipt and possession of licensed material without a valid license would be a violation of 10 CFR 30.3(a). However, in this case: (a) the violation was licensee self-identified; (b) the licensee took prompt corrective action by notifying the NRC requesting a license amendment; (c) the violation was not repetitive as a result of inadequate corrective action; and (d) the violation was not willful. A violation of 30.41(a)(5) was identified for the vendor, Advanced Care Medical (06-30764-01; 030-36099) for transfer of I-125 seeds to St. Anthony's without verification that St. Anthony's, by their license, was authorized to receive the Oncura Model 6711 seeds.

5. PERSONNEL CONTACTED:

#*Brian Pence, Director of St. Anthony's Cancer Center
#*David Keys, Ph.D., RSO and Medical Physicist
Elizabeth Caspari, Medical Physicist
Brenda, Surgical Suite Nurse

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting

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