

Enclosure 6 - INSPECTION RECORD

Region III

Inspection Report No. 2012-001

License No. 21-03210-01

Docket No. 030-02028

Licensee (Name and Address):
St. John Hospital & Medical Center
22101 Moross Road
Detroit, MI 48236-2172

Location (Authorized Site) Being Inspected: 22101 Moross Road, Detroit, Michigan (main hospital) and 19229 Mack Avenue, Grosse Pointe Woods, Michigan (Radiation Oncology)

Licensee Contact: Laura T. Smith, M.S., RSO

Telephone No.: 586-215-5947

Priority: 2 Program Code: 02230

Date of Last Inspection: April 29, 2010

Date of This Inspection: April 19-20, 2012, with continued in-office review through May 10, 2012, to review and discuss a post-treatment plan and the licensee's corrective actions for a violation involving their security documents

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

Next Inspection Date: April 2014 (X) Normal () Reduced

Justification for reducing the routine inspection interval:

Summary of Findings and Actions:

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

Inspector(s): 
Deborah A. Piskura, Health Physicist

Date 5/17/2012

Approved: 
Tamara E. Bloomer, Chief, MIB

Date 5/18/12

Issue Date: 07/27/10
Effective Date: 10/01/10

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

1. AMENDMENTS AND PROGRAM CHANGES:

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
59	6/1/2010	add NORM and NARM materials; clarify location of use for these materials

2. INSPECTION AND ENFORCEMENT HISTORY:

No violations of NRC requirements were identified during the previous routine inspections on April 29, 2010, and April 30, 2008.

3. INCIDENT/EVENT HISTORY:

None.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

This licensee was a large medical institution (600+ bed hospital) authorized to use licensed materials in Sections 35.100, 35.200, 35.300, 35.400, Sr-90 within an IVB unit, and Ir-192 within an HDR unit. The radiation safety program was managed by a dedicated full-time radiation safety officer who splits time between the St. John's hospital sites.

The nuclear medicine department was staffed with six technologists and one pharmacy technician who performed approximately 400-500 diagnostic procedures monthly; the department administered a full spectrum of diagnostic imaging studies. The licensee received unit doses and a Mo-99/Tc-99m generator for kit preparation. The licensee maintained an active therapy program and administered several I-131 dosages for CA, whole body follow up studies, and hyperthyroidism (capsules only). Occasionally, the department administered Y-90 Zevalin dosages (3-5 cases annually) and I-131 Bexxar dosages (3-5 cases annually).

The radiation therapy department was staffed with four authorized physician users, three medical physicists, and two dosimetrists. The licensee used its HDR unit to administer approximately 275 patient treatments per year; these treatments included GYN, lung, esophageal, breast, and prostate cancers. All HDR patient treatments were administered by the attending radiation oncologist, the authorized medical physicist, and a therapy technologist. Service, maintenance, and source exchanges were performed by the HDR device manufacturer. On one occasion in 2010, the licensee administered an I-125 permanent implant using the BrachyMesh system. The licensee maintained numerous Cs-137 "tube" sources previously used for LDR gyn implants. These sources have been in secured storage for several years. The licensee attempted to dispose of these sources in 2011 but lost its bid due to budgetary issues. The inspector advised the licensee to pursue disposal/authorized transfer of these sources.

This inspection consisted of interviews with select licensee personnel; a review of select records; tours of the nuclear medicine and radiation oncology departments; security and accountability of licensed material; use of personnel monitoring; and independent measurements. The inspector observed the administration of an I-131 dosage for thyroid CA. The inspector also observed the licensee staff administer two patient treatments utilizing its HDR unit. The inspector reviewed the post-treatment plan for the BrachyMesh case with physics personnel. The inspection included observations of dose calibrator and HDR QA and safety checks, security of byproduct material, use of personnel monitoring, package receipts and surveys, and patient surveys for compliance with Sections 35.75 and 35.604.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87130, 87131, & 87132

Focus Areas Evaluated: 03.01 - 03.08

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector performed direct radiation measurements in and around the licensee's nuclear medicine hot lab, storage areas, and the HDR treatment room which indicated similar results as noted in the licensee's survey records. While observing QA checks, the inspector measured 5 mR/hr at a small area at the treatment room door. Based on the licensee's workload, occupancy factor for the area, and attenuation by the patient during treatments, the inspector concluded that this area would not exceed Part 20 limits. The licensee committed to evaluate this area for additional shielding. Radiation levels in the unrestricted areas outside the hot labs, the imaging rooms, and the HDR treatment room (with the exception of the threshold of the treatment room door) were indistinguishable from background. The inspector concluded that these radiation levels in the hospital complied with the Part 20 limits. All survey measurements in the restricted areas were comparable to the licensee's survey results.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES: None for the safety inspection.

5. PERSONNEL CONTACTED:

#*Frank Poma, Interim President

*Debbie Condin, Vice President

#*Laura T. Smith, M.S., RSO

*Gary Stoykovich, Director, Imaging

*Deanna Griebe, Imaging Services Manager

Jeff Colvin, M.S., Authorized Medical Physicist

*Carol Hackenberger, M.S., Authorized Medical Physicist

Cynthia Brown, M.D., Ph.D., Authorized User, Radiation Oncologist

Karen Syck-Doppelberger, RN

*Linda Dame, RT(T), Manager, Radiation Oncology

*Lorrie Lipa, M.S., RT(T), Director, Radiation Oncology

Use the following identification symbols:

Individual(s) present at entrance meeting

* Individual(s) present at exit meeting