ENCLOSURE 6

INSPECTION RECORD

Region **III**

Inspection Report No. **2007-001** License No. **21-00943-03**

Licensee (Name and Address): Docket No. **030-01997**

Saint Joseph Mercy Health Systems
St. Joseph Mercy Hospital
P. O. Box 995
Ann Arbor, MI 48106-0995

Location (Authorized Site) Being Inspected: **5301 E. Huron River Drive, Ann Arbor, MI**

Licensee Contact: **Ralph Lieto, MSE, RSO** Telephone No. **734.712.8746**

Priority: **2** Program Code: **02230**

Date of Last Inspection: **1/18/2005**

Date of This Inspection: **2/26-27/2007**

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

Next Inspection Date **2/2009** (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
(X) **Non-cited violations (NCVs)**
( ) Violation(s), Form 591 issued
(X) **Violation(s), regional letter issued**
( ) Followup on previous violations

Inspector(s) _____ Date 3/15/07
Deborah A. Piskura

Approved _____ Date 3/21/2007
John R. Madera, Chief, MIB

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

1. AMENDMENTS AND PROGRAM CHANGES:
(License amendments issued since last inspection, or program changes noted in the license)

AMENDMENT #	DATE	SUBJECT
81-88	**Various**	**various changes and corrections, new AUs and AMPs, new Cs-137 self-contained irradiator**

2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

The last inspection on Jan. 18, 2005, focused on the licensee's corrective actions for a security violation identified during the Sept. 2-3, 2004 routine inspection.

3. INCIDENT/EVENT HISTORY:
(List any incidents, or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.) **NONE**

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

This large hospital (550 bed capacity) was authorized to use materials permitted in Sections 35.100, 35.200, 35.300, 35.400, 31.11, Y-90 liquid calibration sources, and iridium-192 in an HDR unit. In addition, the hospital possessed an MDS Nordion Gammacell 8000 self-shielded irradiator unit containing a cesium-137 source; the licensee's blood lab staff used the irradiator on a daily basis.

The nuclear medicine department was staffed with 12 technologists who performed approximately 9,300 diagnostic nuclear medicine procedures annually. The licensee received unit doses (for cardiac studies) from a licensed nuclear pharmacy and used a Mo-99/Tc-99m generator for kit preparation. The department administered a full spectrum of diagnostic imaging studies. Typically in a year, the hospital treated 120 cases of hyperthyroidism, 30 cases of thyroid carcinoma, and 50-60 whole body CA follow up studies. The licensee obtained its radioiodine from a licensed nuclear pharmacy in capsule form; only for rare, patient-specific cases would the licensee use NaI-131 in liquid form. The licensee retained the services of a consultant physicist who audited the nuclear medicine radiation safety activities on a quarterly basis.

The radiation therapy department was staffed with 4 medical physicists and 5 dosimetrists. The hospital had not used its Cs-137 sources for temporary implants since the previous inspection. The department administered an average of 10 beta-emitting radiopharmaceutical dosages annually. The department used I-125 and Pd-103 for permanent prostate implants to treat approximately 5 cases per year.

The department possessed an HDR unit and administered approximately 120-150 patient treatments per year; the majority of these treatments were for bronchial, breast, prostate, and gynecological cancers. All HDR patient treatments were administered by the attending radiation oncologist and an authorized medical physicist. Source exchange, maintenance, and repairs on the HDR unit were performed by the manufacturer.

This inspection consisted of interviews with licensee personnel, a review of select records, tours of the blood bank, nuclear medicine, and radiation oncology departments, and independent measurements. The inspector observed the administration of several diagnostic nuclear medicine procedures. The inspection included observations of HDR safety checks, dose calibrator QA checks, security of byproduct material (not subjected to the Order for the Increased Controls), use of personnel monitoring, and package receipts and surveys. The inspector observed one HDR brachytherapy treatment. The inspector reviewed the written directive for the procedure and observed the patient treatment and patient surveys at the conclusion of the treatment. The inspector interviewed two physician authorized users and a nurse who attended to the patient.

The inspection included a review of the licensee's actions in response to the Order for Increased Controls (EA-05-090), dated Nov. 14, 2005. The results of the IC inspection were documented in IR 030-01997/2007002.

RSO conducted quarterly audits of the radiation oncology department's radiation safety activities. The RSO reviewed written directives, patient surveys, sealed source leak tests and inventories, monthly HDR spot checks and full calibrations, training, and personnel exposures. The inspector reviewed select RSO audit reports and noted the RSO identified that the physical inventories were not performed between April 30 , 2004 and June 13, 2006. According to the RSO and the medical physicists, the staff failed to recognize that although the sources had not been used since for several years and remained in secured storage, the licensee was still required to perform semi-annual physical inventories. The staff confused the provisions in Section 35.67(f) which allows the licensee not to perform leak tests on sealed sources in storage. The staff erroneously believed that since their sources were "in storage," they were not required to perform semi-annual physical inventories as well. The medical physics staff added semi-annual inventories as a task/reminder to the department calender.

The inspector's review of select RSO audit reports also revealed that the RSO identified several missing monthly safety checks for the HDR unit. According to the RSO, the medical physics staff failed to perform monthly HDR safety checks during Jan., July, Nov. & Dec. 2005 and the department continued to treat patients using the HDR unit. The monthly safety checks include performing a source output check in accordance with historical licensing requirements. Note: a monthly source calibration/output check is not longer required in accordance with current Part 35 or the license renewal application. Discussions with the medical physicists revealed that during 2005, the department was staffed with one authorized medical physicist who was also involved with the commissioning of a new LINAC unit at a satellite clinic. Other medical physicists at the hospital failed to recognize the regulatory requirements for performing the monthly safety checks. The AMP provided training to the staff physicists on the requirements to

perform monthly safety checks with emphasis on regulatory requirements verses recommendations from the AAPM.

However, the RSO again identified that the staff failed to conduct monthly safety checks on the HDR unit in Sept. 2006 and the department continued treating patients. Discussions with the physics staff revealed that the Sept. 2006 safety check were not performed due to unavailable calibration equipment. Since the department performed a source output check concurrently with the monthly safety checks and their dosimetry equipment was unavailable in Sept. 2006, the staff failed to perform the required safety checks. According to the chief physicist, when the dosimetry equipment was send out for calibration in late August 2006, the electrometer was damaged in shipment and required additional repairs which resulted in unexpected delays in its return. In light of these delays, the chief physicist recommended that the department purchase an additional electrometer so that sufficient dosimetry equipment is available while other dosimetry equipment is sent out for calibration. In late 2006, the department acquired a second electrometer and the physics staff believed that the availability of additional equipment will prevent future lapses in monthly safety checks and monthly source calibrations/output checks. The inspector advised the physicists that based on the commitments in the license for performing monthly safety checks which did not include monthly source calibration/output checks, it was unnecessary to delay conducting HDR unit safety checks due to unavailable dosimetry equipment.

The maximum whole body and extremity exposures (in millirem) were recorded as follows:

	2005	2006	-1/31/2007
Whole Body	**453**	**540**	**70**
Extremity	**8,870**	**6,400**	**620**

2. INSPECTION SCOPE

INSPECTION PROCEDURE(S) USED: **87122, 87130, 87131, 87132**

INSPECTION FOCUS AREAS: **03.01, 03.02, 03.03, 03.04, 03.05, 03.06, and 03.07**

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

The inspector performed direct radiation measurements in and around the licensee's hot labs and dose prep areas which indicated similar results as noted in the licensee's survey records, <2 mR/hour. Maximum levels were measured at the surface of the hospital's generator storage area, 1.2 mR/hr. Radiation levels in the unrestricted areas outside the hot lab and the scan rooms were at background (<0.02 mR/hr). These surveys confirmed that the licensee complied with Part 20 limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:
(State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

A regional letter was issued to the licensee containing a notice of violation. A non-cited violation is also discussed in the regional letter.

Condition 21.A. of License No. 21-00943-03 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in a letter, dated August 24, 2005, with attachments.

Item 8.18 - "Therapy Unit - Calibration and Use" of letter, dated August 24, 2005, states that the licensee has developed procedures for performing periodic spot checks of the HDR machine as required by 10 CFR 35.643. See Appendix II for supporting information describing the licensee's authorization renewal of its HDR program.

Item B.2., "Safety Checks" of Appendix II, "High Dose Rate (HDR) Remote Afterloader Program," requires, in part, that the following safety checks be performed in a period not to exceed one month prior to any patient treatment: (1) Source position; (2) Timer accuracy and linearity; (3) Source guide tubes lengths confirmed; and (4) Back up battery test.

Contrary to the above, during January, July, November and December 2005, and September 2006, the licensee did not perform any of the required safety checks on its HDR unit and patients were treated during these months.

Non-cited violation
One violation of NRC requirements was identified concerning the licensee's failure to conduct sealed source inventories of the Cs-137 brachytherapy sources at semi-annual intervals, as required by Section 35.67(g). According to the RSO's audit findings, the physical inventories were not performed between April 30 , 2004 and June 13, 2006. The medical physics staff failed to recognize that although the sources had not been used since 2002 and remained in secured storage, the licensee was still required to perform semi-annual physical inventories. The staff confused the provisions in Section 35.67(f) which allows the licensee not to perform leak tests on sealed sources in storage. The staff erroneously believed that since their sources were "in storage" they were not required to perform semi-annual physical inventories as well. The medical physics staff added semi-annual inventories as a task/reminder to the department calender.

5. PERSONNEL CONTACTED:
[Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone).

***Julie MacDonald, MS, RN, Sr. Vice President, Patient Care Services/COO**
#*Ralph Lieto, MSE, Radiation Safety Officer
#*Kathleen Kasperek-Korelis, Oncology Program Director
***Alisa Michalishyn, MT(ASCP) Service Delivery Leader, Clinical Laboratory**
***Jim Knauf, Business Line Leader, Radiology Services**
Michelle Hazard, Service Delivery Leader, Nuclear Medicine

***Scott Hunter, M.S., Authorized Medical Physicist**
***Aurelian Belecciu, M.S., Authorized Medical Physicist**
+Matthew McMullen. M.S., Authorized Medical Physicist
Christine Dickinson, M.D., Radiologist
Salam A. Jafer, M.D., Radiation Oncologist
Swati Dutta, M.D., Radiation Oncologist
Several nuclear medicine and medical technologists were also contacted

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