Enclosure 6 - INSPECTION RECORD

Region III

Inspection Report No. 2011-001

License No. 21-02802-03
Docket No. 030-02022

Licensee (Name and Address):

Providence Hospital
Department of Nuclear Radiology
16001 W. Nine Mile Road
Southfield, MI 48037

Location (Authorized Site) Being Inspected: Main Hospital, Southfield, MI; 47601 Grand River Avenue, Novi, MI; and TJS at St. Johns Macomb Hospital, Warren, MI

Licensee Contact: Allan D. Fraiberg, M.D., RSO Telephone No.: 248-849-8622

Priority: 3 Program Code: 02120

Date of Last Inspection: Sept. 16, 2010, (with continued in-office review through Mar. 17, 2011)
Date of This Inspection: Aug. 9-10, 2011

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

Next Inspection Date: 8/2014 (X) Normal ( ) Reduced

Justification for reducing the routine inspection interval:

Summary of Findings and Actions:

(X) 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
( ) Violation(s), regional letter issued
(X) Follow up on previous violations

Inspector(s): ***/RA/*** Date 9/8/11
Deborah A. Piskura, Health Physicist

Approved: ***/RA/*** Date 9/8/11
Tamara E. Bloomer, Chief
Materials Inspection Branch

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

1. AMENDMENTS AND PROGRAM CHANGES:

AMENDMENT #	DATE	SUBJECT
69	3/6/2011	delete one AU
70	6/17/2011	add mobile PET service
71	7/14/2011	add new AU

2. INSPECTION AND ENFORCEMENT HISTORY:

The previous inspection on September 16, 2010, was conducted to review the events and circumstances associated with a medical event that Providence Hospital (the licensee) reported to the U.S. Nuclear Regulatory Commission (NRC) on September 2, 2010. During a palliative treatment of a rectal tumor with an anal extension on August 30, 2010, the licensee mistakenly implanted the iodine-125 (I-125) seeds superior to the intended site. One apparent violation of Title 10 of the Code of Federal Regulations (CFR) 35.41(a) was identified involving the licensee's failure to develop adequate procedures to provide high confidence that a manual brachytherapy I-125 seed implant therapy was performed in accordance with the written directive.

No violations of NRC regulatory requirements were cited during two prior routine inspections conducted on October 19, 2006, and August 19, 2008.

3. INCIDENT/EVENT HISTORY:

None. The licensee has not reported any medical events since the previous reactive inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

This routine inspection included a review of the licensee's corrective actions in response to escalated enforcement action involving a medical event.

This licensee was a large medical institution and operated two community hospitals in Novi and Southfield as well as a mobile PET imaging service for its hospitals within the St. John Health System. Nuclear medicine imaging and therapy was performed at both hospitals. The majority of implants were administered at the Novi hospital site.

The nuclear medicine department was staffed with four full-time technologists who performed approximately 250-300 diagnostic nuclear medicine procedures per month. The majority of these procedures were bone, gastric emptying, cardiac, gall bladder, and lung imaging (using Xe-133). The licensee received unit doses and bulk Tc-99m for kit preparation. Typically, in a year the hospital administered 10-12+ cases of

hyperthyroidism and 5-10 whole body cancer follow up studies. Radioiodine was obtained from the radiopharmacy in capsule form. The hospital released its I-131 patients in accordance with the provisions of Section 35.75. The licensee retained the services of a consulting physicist who audited the nuclear medicine radiation safety program on a quarterly basis (last audit 5/31/2011, with no violations or concerns identified).

The radiation therapy department was staffed with one authorized physician user, four medical physicists, and four dosimetrists. The licensee administered 100+ I-125 or Pd-103 permanent prostate implants annually. Occasionally, the licensee administered permanent I-125 interstitial implants for other cancers including brain and rectal cancers.

This inspection consisted of interviews with licensee personnel, a review of selected records, a tour of the nuclear medicine department, and independent measurements. The inspection included observations of dose calibrator QA checks, security of licensed material, and use of personnel monitoring.

This inspection verified the licensee's corrective actions which included revisions it its written procedure for interstitial brachytherapy treatments to require: (1) the use of tissue markers during treatments that require the use of fluoroscopy alone to confirm source placement, and (2) a needle depth check using two different measurements for verification during treatments that require the use of fluoroscopy alone. To ensure the written directive will be administered with high confidence in the future, the licensee provided training for the above to all appropriate authorized users. No violations were identified during this follow up inspection and the previous violation was considered closed.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87130, 87131, and 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 and storage area which indicated similar results as noted in the licensee's survey records. Maximum levels were measured at the surface of the L-block within the hot lab. Radiation levels in the unrestricted areas outside the hot lab, the imaging rooms, and the source room 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:

The inspector reviewed the licensee's policies and procedures for administering and monitoring xenon-133. Xenon was administered occasionally (1-2 cases per week) to patients for lung studies. Xenon vials were stored within a vented hood in the hot lab which is maintained at negative airflow. Xenon was administered using a shielded trapping delivery system in two approved imaging rooms (Rooms 4 and 5) that were also maintained at negative airflow. All areas were xenon was stored or administered were posted with xenon clearance times or evacuation times; in case of a spill these clearance times sign would indicate the time to evacuate the room, close the room and allow enough air exchanges to clear the room of any xenon gas. The air flow for these rooms and the ventilation hood are checked periodically by a ventilation company and verified by the licensee's consultant during her quarterly program audits. These air flow checks were coordinated by the hospital management to be performed for not only the nuclear medicine department but other critical areas (surgery, intensive care, etc.) within the hospital. Based on the above, the inspector concluded that the licensee maintained its processes and equipment in accordance with Part 20.

The inspector expressed concern, based on the staff's initial response to questions concerning medical events and their ability to recognize medical events involving prostate implants. Specifically, the inspector received multiple conflicting responses from the licensee staff regarding how the staff evaluated post-treatment plans to determine if an implant was administered in accordance with the physician's written directive. The licensee management acknowledged the inspector's assessment and committed to revising its procedures for administrations requiring a written directive to clarify the meaning of the prescribed dose to the treatment site. The licensee also intended to discuss these procedure revisions during the next physics staff meeting.

5. PERSONNEL CONTACTED:

*Laura Daily-Pelle, MSA, RTT, Director, Radiation Oncology and Healing Arts
*Karen A. North, MSBA, Director, Providence Cancer Institute
#Joseph R. Hurshe, Vice President, Operations
*Allan D. Fraiberg, M.D., Radiation Safety Officer
Patrick W. McLaughlin, M.D., Radiation Oncologist
Paul Heckman, Ph.D., Sr. Medical Physicist
*Kristen Kaska, CNMT, Chief Technologist
*Lou Bischoff, Director, Radiology
*#Maureen Goorman, Manager, Radiology
Vrinda Narayana Ph.D., Chief Medical Physicist
Bin Yao, M.S., Medical Physicist
Eric Short, CMD, Dosimetrist
Several nuclear medicine technologists were also contacted
Michelle Kritzman, M.S., Consultant, Medical Physics Consultants, Inc.

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