

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No. 03001246/2010001
Docket No. 03001246
License No. 06-00854-03
Licensee: St. Francis Hospital and Medical Center
Location: 114 Woodland Street, Hartford, Connecticut
Inspection Dates: June 28, 2010, June 30 - July 1, 2010, and
August 20, 2010 (exit meeting)
Date(s) Follow-up
Information Submitted: July 7 and 26, 2010

Inspector: **/RA by Sandra Gabriel For/** 8/23/10
Tara L. Weidner date
Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Approved By: **/RA by Sandra Gabriel For/** 8/23/10
Marc S. Ferdas, Chief date
Medical Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

St. Francis Hospital and Medical Center
NRC Inspection Report No. 03001246/2010001

A routine, unannounced inspection was conducted at St. Francis Hospital and Medical Center (St. Francis) in Hartford, Connecticut on June 28 and June 30 through July 1, 2010. Additional information, contained in correspondence from St. Francis on July 7, and 26, 2010, was also reviewed. The inspection consisted of a review of the organization and scope of activities associated with the use of radioactive materials (RAM) within the following departments at St. Francis: Nuclear Medicine, Radiation Oncology, Research and Development and Collaborative Laboratory Services. The inspector conducted interviews with St. Francis personnel, observed day-to-day operations, toured the facilities, and reviewed documents and procedures related to the RAM programs within St. Francis.

Based on the results of this inspection, three apparent violations of NRC requirements were identified. Specifically,

1. St. Francis did not ensure that an authorized medical physicist (AMP) was physically present during the initiation and continuation of patient treatments involving the high dose rate remote afterloader (HDR), as required by 10 CFR 35.615(f)(2);
2. St. Francis personnel did not secure the HDR console keys when the unit was unattended, as required by 10 CFR 35.610(a)(1); and
3. St. Francis personnel did not monitor the external surface of labeled RAM packages for contamination, as required by 10 CFR 20.1906(b)(1).

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope

A routine, unannounced inspection was conducted at St. Francis on June 28 and June 30 through July 1, 2010. Additional information, contained in correspondence from St. Francis on July 7, and 26, 2010, was also reviewed. The inspection consisted of a review of the organization and scope of activities associated with the use of RAM within the following departments at St. Francis: Nuclear Medicine, Radiation Oncology, Research and Development and Collaborative Laboratory Services. The inspector conducted interviews with St. Francis personnel, observed day-to-day operations, toured the facilities, and reviewed documents and procedures related to the RAM programs within St. Francis.

b. Observations and Findings

Radioactive Material Program Organization and Program Scope

The St. Francis program includes a full range of nuclear diagnostic studies and therapeutic procedures in accordance with 10 CFR 35.100, 200, 300 and radiation oncology services in accordance with 10 CFR 35.400 and 600. St. Francis also performs research and development activities and irradiation of blood and blood products. Audits of the activities performed within each department are reviewed by department staff and results are provided to the Radiation Safety Officer (RSO). The RSO considers the department reviews as part of the annual audit of the radiation safety program. The inspector noted that the RSO does not conduct performance based reviews of each functional area as recommended in NUREG-1556, Volume 9, Revision 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses. The RSO is a consultant physicist present at the hospital one day per week.

The Radiation Oncology department is staffed by three authorized medical physicists (AMP) and two dosimetrists. On average, four iodine-125 prostate brachytherapy treatments are performed each month using real-time planning in the operating room. All implant patients are released in accordance with the requirements in 10 CFR 35.75 and return for a post implant Computerized Tomography (CT) scan 30 days following implantation. A strontium-90 eye applicator, for the treatment of pterygium, is currently in storage. Activities authorized by 35.600 include the use of a low dose rate remote afterloader (LDR) using cesium-137 and a HDR using iridium-192. The LDR unit was last used in June 2010. St. Francis personnel stated that the LDR unit has become obsolete because the manufacturer no longer stocks parts and that they intended to decommission the LDR unit. The HDR unit is used primarily for the treatment of gynecologic cancers and infrequently for endobronchial. Approximately, twelve fractions per month are performed.

The Nuclear Medicine department performs a wide range of diagnostic studies. The department is divided into three functional areas, general nuclear medicine, cardiology, and positron emission tomography (PET) and is staffed by eight nuclear medicine technologists (NMT) that rotate through each area. Approximately 500 studies are performed each month. Two technetium-99m (Tc-99m) generators are received from Covidien each week for the preparation of doses. Therapeutic iodine-131 (I-131) procedures, requiring a written directive, are performed monthly. Approximately 30% of the I-131 therapy patients are treated in-house and patients who are released are done so in accordance with the requirements in 10 CFR 35.75. All doses are assayed in the dose calibrator prior to administration.

In December 2008, a PET suite was opened at St. Francis. Prior to that, PET scans were performed by a mobile PET licensee that came to the hospital weekly. The PET suite is comprised of a hot lab, camera room, and multiple quiet rooms. The radiopharmacy delivers fluorine-18 directly to the PET hot lab. The NMT that is assigned to that area is responsible for surveying incoming RAM packages.

Research and development activities at St. Francis are limited to microcurie quantities of phosphorus-32 (P-32) used for labeling cells. The P-32 is stored in shielded containers in laboratory refrigerators. Access to the laboratory area is controlled by a door access system.

The Collaborative Laboratory Services Department operates the blood bank at St. Francis where blood and blood products are irradiated. The blood bank is staffed 24 hours a day.

Radiation Oncology

The inspector observed St. Francis personnel perform spot-checks (quality assurance testing) for the HDR prior to patient treatment on July 1, 2010. The inspector noted that at the completion of the spot-check procedure St. Francis personnel did not remove the HDR key from the console prior to leaving the HDR area. 10 CFR 35.610(a)(1) requires, in part, that the licensee secure the HDR console and console keys when the unit is not attended. The inspector also noted that in order to access the HDR control, an individual would need to have the keys and the console password in order to activate the HDR unit. The inspector saw no evidence that the password was unprotected.

The inspector also observed a patient undergoing an HDR treatment on July 1, 2010 and noted when the treatment was initiated the AMP was not present at the console. The inspector informed the authorized user (AU) that the AMP is required to be present at the initiation of an HDR treatment per NRC requirements. The AMP was immediately called to the HDR unit for the continuation of the treatment fraction. 10 CFR 35.615(f)(2) requires, in part, that an AU and an AMP be physically present during the initiation of all patient treatments involving the HDR unit and that an AMP and either an AU or a physician under the supervision of the AU, who has been trained in the operation and emergency response for the unit, be physically present during the continuation of all patient treatments involving the HDR unit. The AMP was in another area of the radiation oncology department, not within the range of normal speaking voice, at the initiation of

the patient treatment. During interviews with the inspector concerning the conduct of HDR treatments at St. Francis, the AMP stated that she misinterpreted the regulation and believed that the dosimetrist, who is under her supervision and who has been trained in the operation and emergency response for the unit, could be present at the unit in place of the AMP. The AMP also stated that the dosimetrist was initially trained in the HDR operation and emergency response in 2006 and that she had participated in annual training ever since. According to the AMP, the three AMPs and the dosimetrist rotate responsibility for patient treatments. Therefore, the AMP confirmed that the dosimetrist would have been present at patient treatments periodically since 2006. Based on the information provided, the inspector concluded that the AMP was also not physically present during previously performed HDR treatments.

Nuclear Medicine

The cardiology area is remotely located from the Nuclear Medicine department. Bulk Tc-99m is transported to the cardiology hot lab and doses are prepared there or unit doses are received in Nuclear Medicine and transported to cardiology. The cardiology hot lab has limited space and maintains a labeled, lead lined waste storage bin in the camera room. The inspector noted that the key was being maintained in the waste storage bin lock. During interviews with the inspector, St. Francis personnel stated that the key is always in the lock and that the camera room is always occupied by at least one NMT. They also stated that the area is locked at the end of each day. The inspector determined that St. Francis was able to maintain adequate control of radioactive material in the cardiology area, however based on the inspector's observations St. Francis revised its practice of storing the key in the storage bin lock in order to improve their security of stored RAM.

The inspector requested that the NMT demonstrate the procedure for a package receipt. The NMT surveyed the package at 3 feet and the surface with an appropriate survey instrument. The inspector noted that the NMT did not perform a wipe test of the package during the demonstration. The inspector discussed this with the NMT and they stated that they did not perform a wipe test on packages received in the PET suite because the PET hot lab did not contain a counter. The NMT further stated that they did perform wipe tests on packages received in the Nuclear Medicine department because the hot lab contained the necessary equipment. 10 CFR 20.1906(b)(1) states that, each licensee shall monitor the external surface of a labeled package for radioactive contamination. A package containing 15 millicuries of F-18 is a labeled Yellow II package, and therefore needed the external surface of the package to be monitored for contamination.

Corrective and Preventive Actions

During the on-site inspection and in subsequent correspondence dated July 7 and 26, 2010, St. Francis described the following corrective and preventive actions associated with the observations and findings of the inspector:

1. St. Francis revised their HDR operating procedure to clearly state that an AMP must be physically presented during all HDR treatments. In addition, each AMP was required to review the procedure change;
2. St. Francis committed to logging out of the HDR computer software and removing and securing the HDR console key when the unit is not in use or attended; and
3. St. Francis revised their procedure for ordering and receiving RAM to include step-by-step instructions on the proper technique for wiping labeled packages. In addition, each NMT was required to review the revised procedure and participate in a demonstration of the process for performing surveys and wipe tests.

c. Conclusions

Based on the results of this inspection, three apparent violations of NRC requirements were identified. Specifically,

1. 10 CFR 35.615(f)(2) requires, in part, that an AMP be physically present during the initiation of all patient treatments involving the HDR unit and an AMP to be physically present during continuation of all patient treatments involving the unit.

Contrary to the above, St. Francis did not ensure that an AMP was physically present during the initiation and continuation of patient treatments involving the HDR. Specifically, on July 1, 2010 the AMP was not physically present during the initiation of a patient treatment involving the HDR unit. In addition, on occasions prior to July 1, 2010, an AMP was not physically present during the initiation and the continuation of patient treatments involving the HDR unit. During HDR treatments the AMP would be located in another area of the Radiation Oncology department, not within the range of normal speaking voice, at the initiation and continuation of patient treatment.

2. 10 CFR 35.610(a)(1) requires, in part, that the licensee secure the HDR unit, the console, the console keys, and the treatment room when not in use or unattended.

Contrary to the above, on July 1, 2010, St. Francis did not secure the HDR console keys when the HDR unit was not in use or when it was unattended. Specifically, following the completion of the spot check procedure, St. Francis personnel did not remove the HDR console key prior to leaving the HDR console area.

3. 10 CFR 20.1906(b)(1) requires, in part, that the licensee monitor the external surfaces of a labeled package for radioactive contamination.

Contrary to the above, as of July 1, 2010, St. Francis did not monitor the external surfaces of labeled packages for radioactive contamination. Specifically, a NMT demonstrated the routine incoming package surveys for labeled packages received in the PET hot lab and did not perform the require wipe test. In addition, they stated that they had not performed wipe tests of RAM packages previously received in the PET hot lab.

II. Exit Meeting

At the conclusion of the site inspection on July 1, 2010, the inspector briefed members of St. Francis management on the scope of the inspection and the inspector's preliminary observations. St. Francis acknowledged the inspector's observations and immediately initiated corrective actions. An exit meeting was held by telephone on August 20, 2010 with Robert Falaguerra, Vice President, Facilities and other members of St. Francis management, and other members of St. Francis staff, to discuss the results of the inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

- ** ++Kathleen Smith – Assistant Director of Radiology
 - ** ++Leonard Quartararo – Director, Radiology and Imaging Services
 - ** Ernie Canalas – Director, Research
 - ** Anna Ramoya – Research
 - ** Kathleen Roche – Executive Vice President and COO
 - ** ++Jacqueline Harder – Director, Radiation Therapy Operations
 - ** ++Bob Varsanik – Assistant RSO, Supervisor, Nuclear Medicine
 - **++ Ellen Wilcox, Ph.D. – Chief Medical Physicist
 - ** Gregory Hisel – Radiation Safety Officer
 - ** ++Kathleen Luczyk – Chief Operating Officer, Collaborative Laboratory Services
 - ** Mary Onoroski – Site Manager, Collaborative Laboratory Services
 - ** ++Robert Falaguerra – VP Facilities/Hospital Safety Officer
 - James D. Slavin, M.D. – Chairman, Radiation Safety Committee
 - Stephanie Gambon – NMT
 - Cathy Ross – NMT
 - Tamika Joseph-Reyes – NMT
 - Dean Alvarez – NMT
 - Kristen Pullis - Nurse
 - David Crowell - Director of Environmental Services
 - Claudia Putzhammer – Dosimetrist
- ** Attended briefing conducted on July 1, 2010
- ++Attended telephonic exit meeting on August 20, 2010