Enclosure 6 - INSPECTION RECORD

Region III

Inspection Report No. **2010-001** License No. **21-12930-01**
Docket No. **030-02140**

Licensee (Name and Address):

Henry Ford Wyandotte Hospital
2333 Biddle Avenue
Wyandotte, MI 48192

Location (Authorized Site) Being Inspected: **2333 Biddle Avenue, Wyandotte, MI**

Licensee Contact: **Donald Peck, Ph.D., RSO** Telephone No.: **313-916-7042**

Priority: **3** Program Code: **02120**

Date of Last Inspection: **August 22, 2007**
Date of This Inspection: **September 22, 2010 (with continued in-office review through October 26, 2010)**

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

Next Inspection Date: **09/2013** (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): _____ Date 10/28/2010
Deborah A. Piskura, Health Physicist

Approved: _____ Date 11/01/10
Tamara E. Bloomer, Chief, MIB

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

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

No licensing actions have been issued since the previous NRC inspection.

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

No violations were identified during the last two previous routine inspections conducted on July 21, 2004, and August 22, 2007.

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.)

This routine inspection included a review of the licensee's notification of use of Iodine- 131 (I-131) by an unauthorized physician. On September 3, 2010, the licensee notified the NRC HOO that a physician prescribed and administered six I-131 dosages and this individual was not specifically listed on the license as an authorized user for Section 30.300 materials; the physician was listed on the license for Sections 35.100 and 35.200. The licensee's written report (ML 1026407090) dated September 17, 2010, described the discovery and investigation of the unauthorized administrations. The licensee also provided additional information on the physician's training and experience via e-mail on October 8 and 19, 2010 (ML 102920638). One violation of NRC requirements was identified.

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 licensee was a large medical institution affiliated with the Henry Ford Hospital System. A dedicated radiation safety office managed the radiation safety program at its various sites, including the Henry Ford Wyandotte Hospital. The radiation safety office performed quarterly audits of the radiation safety program.

The nuclear medicine department was staffed with four full-time technologists and one part-time technologist who performed approximately 600 diagnostic nuclear medicine procedures per month. The majority of these procedures were bone, cardiac, gall bladder, and lung imaging (using Xe-133). The licensee received a Mo/Tc-99^{m} generator each week. Typically, in a year the hospital treated 10 patients with I-131 for thyroid cancer and 10-15+ cases of hyperthyroidism, and 10-15 whole body cancer follow up studies. Radioiodine was obtained from the radiopharmacy in capsule form. The hospital released I-131 patients in accordance with the provisions of Section 35.75.

The radiation therapy activities were limited to permanent prostate implants using iodine-125. The implants were performed by one authorized user supported by one medical physicist. The licensee performed an average of 5 implants each year with a prescribed dose of 145 Gy for monotherapy or 108 Gy as a boost to LINAC treatment. The inspector reviewed a selected sample of 15 pre- and post-treatment plans to determine if the administered dose was in accordance with the written directive. During this inspection, the inspector identified ten patient brachytherapy post-treatment plans where the administered dose appeared to exceed the prescribed dose by more than 20 percent. All written directives specified a prescribed dose to the prostate of "145 Gy, Isodose." The D90s ranged between 122.43 to 169 percent. The licensees procedures entitled, "Quality Management Program Brachytherapy Module" (undated) did not specify how the dose to the treatment site was assigned or the methods used to evaluate the administered dose to the prostate (D90 or V100). The licensee's authorized user and medical physicist stated their position, based on their understanding through information obtained in professional meetings and journal articles, that there was no upper bounding dose limits for prostate implants. According to the authorized user, the staff evaluated the cases based on a comparison of the pre-plan V100 and D90 to the post-plan V100 and D90; if these pre- and post-plan values are in 20 percent agreement, the case is considered acceptable. <u>This issue is considered an Unresolved Issue.</u>

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. The inspector observed the licensee personnel prepare, assay, and administer two unit doses for cardiac testing procedures (one stress and one resting).

On September 3, 2010, the licensee notified the NRC HOO that a physician prescribed and administered six I-131 dosages and this individual was not specifically listed on the license for 30.300 materials. The dates of these administrations were between April 26, 2010, and August 27, 2010, and included whole body follow up scans, hyperthyroid and thyroid carcinoma treatments. The licensee identified this issue during a routine audit of the radiation safety program. Previous program audits focused on other aspects of the written

directives and failed to identify that the physician had previously administered I-131 dosages without proper authorization. The licensee expanded the scope of its audit to include a review of all written directives generated since 2005. The rationale being that the physician in question became an authorized user at the hospital in 2005. The licensee identified a total of 16 cases where the physician wrote written directives for various I-131 treatments/procedures. These cases were administered independently by the physician between April 24, 2008, and August 27, 2010, and included eight whole body cancer follow up studies, three hyperthyroid treatments, and five carcinoma treatments. Once the licensee identified that the physician was not an authorized user of Section 35.300 materials, the assistant RSO instructed the nuclear medicine staff on the terms of the license and how to recognize the authorization terms for the authorized physician users. The licensee also developed a listing of physician users authorized for Section 35.300 materials and posted the listing in the hot lab.

Interviews with the physician and a review of the physician's training and experience determined that physician was ABR certified in Diagnostic Radiology in 1996. The individual completed his training during a residency between 1992 and 1996, and at that time would have satisfied the training and experience criteria for Section 35.300 materials. During his residency, the physician participated in 20 cases of hyperthyroidism/follow up studies and 16 cases of thyroid carcinoma. When the physician applied for privileges at the hospital in 2000, the nuclear medicine department head noted that the physician completed a residency at the same hospital as the department head. The department head assumed that the physician would have the same training and experience and case studies as he and approved the individual for diagnostic and therapeutic radiopharmaceuticals. This in-house credentialing is reviewed every two years and the physician was approved for therapeutic radiopharmaceuticals each time. However, when the licensee submitted a license renewal application in 2005, the physician was authorized for Sections 35.100 and 35.200 materials only (based on his board certification and previous reference to another license, using 35.100 and 35.200 materials, where he was an authorized user). A review of the physician's training and experience, documented in a Form 313A, Preceptor Statement, showed that the individual personally participated in 20 cases of hyperthyroidism and 16 cases of thyroid carcinoma.

There was no evidence that medical events occurred as a result of the unauthorized administrations of I-131. The inspector reviewed each written directive by the physician and found the documents contained all the requirement information (with the exception of the signature of an authorized user). The inspector reviewed all written directives generated since 2005, and found no other instances of unauthorized physicians using I-131.

The root cause regarding the violation was due to the misunderstanding of the terms of its NRC license by the nuclear medicine staff. The physician was acting in the department head's absence and was approached by the staff to treat a patient. The physician asked the staff if he was listed on the licensee with the

intent that he was an authorized user for therapeutic I-131 (Section 35.300 material). A nuclear medicine technologist informed the physician that he was listed by name on the license and based on her understanding of the licensee terms, mistakenly informed the physician that he was authorized for Section 35.300 material. The nuclear medicine staff failed to confirm their understanding with the licensee's radiation safety department. In addition, the licensee's audits missed opportunities to identify the violation. The majority of the I-131 treatments were administered by another authorized user. The audits focused other aspects of the administration such as patient identification, dosage, assay, pregnancy testing, etc. Therefore, the licensee's previous audits failed to identify that the physician had administered materials outside his licensed authorization.

2. SCOPE OF INSPECTION:
(Identify the inspection procedure(s) used and focus areas evaluated. If records were reviewed, indicate the type of record and time periods reviewed)

Inspection Procedure(s) Used: **87130, 87131, and 87132**

Focus Areas Evaluated: **03.01 - 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 lab which indicated similar results as noted in the licensee's survey records. Maximum levels were measured at the surface of the L-block. Radiation levels in the unrestricted areas outside the hot lab and the imaging rooms 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:
(State the requirement, how and when the licensee violated the requirement, and the licensee's proposed corrective action plan. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

One violation of NRC requirements was identified during this inspection for unauthorized use of materials by a physician user. This issue was discussed with FSME on October 21, 2010, and confirmed that the violation should be categorized as a Severity Level IV.

Condition 12.B. of License Number 21-12930-01, specifically names individuals as authorized users for specified materials in Title 10 of the Code of Federal Regulations (CFR), Part 35.

10 CFR 35.59, "Recentness of Training," states, in part, that the training and experience of an individual must have been obtained within 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Contrary to the above, on 16 occasions, between April 24, 2008, and August 27, 2010, a physician administered iodine-131, an unsealed byproduct material, as specified in Section 35.300 and the individual was not listed on the license as an authorized user of this material. Specifically, the physician was only authorized on the license for materials specified in Sections 35.100 and 35.200. In addition, the physician's training and experience with material specified in Section 35.300 was obtained between 1992 and 1996, a period greater than seven years from the dates the physician used this material, as required by Section 35.59, "Recentness of Training."

This is a Severity Level IV Violation (Section 6.12).

The inspector also identified prostate brachytherapy post-treatment plans where the administered dose to the treatment site appeared to exceed the prescribed dose by more than 20 percent. Due to questions regarding the methodology for assigning the dose to the treatment site, this issue has been identified as an unresolved issue.

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

***# Michael J. Anctil, Administrator, Outpatient Services**
***#+ Dorothy Barr, RT(R), Director, Radiology**
Kenneth D. Barthold, M.D., Authorized User
Shannon Dehring, CNMT
***+ Misbah Gulam, M.S., Medical Physicist**
***# +Alan M. Jackson, M.S., CHP, Assistant Radiation Safety Officer**
James Lasich, CNMT
***Teamon Nurushev, Ph.D., Medical Physicist**
Wendy Owczarzak, CNMT
*** +Donald Peck, Ph.D., Radiation Safety Officer**
+Deepak Pradhan, M.D., Authorized User
*** James J. Sexton, FACHE, President and CEO**
+Cheryl Taylor, RN, Administrator, Nursing
***# Mayur Vaya, CNMT**
Michael F. Zydeck, M.D., Authorized User

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at the on-site exit meeting
+Individuals who participated in the 10/26/2010 telephonic exit meeting