ENCLOSURE 6

INSPECTION RECORD

Region III

Inspection Report No. **2007-001** License No. **21-32449-01**

Licensee (Name and Address): Docket No. **030-36259**

St. John Detroit Riverview Hospital
Nuclear Medicine Department
7733 E. Jefferson Avenue
Detroit, MI 48214

Location (Authorized Site) Being Inspected: **7733 East Jefferson Avenue, Detroit, MI**

Licensee Contact: **Mark Bradford, RN, Manager, Cardiology Services** Telephone No. **313.499.4048**

Priority: **5** Program Code: **02121**

Date of Last Inspection: **1/23/2004**

Date of This Inspection: **1/31/2007 with continued in-office review through 2/9/2007 to review and discuss the licensee's corrective actions for the violations identified during this inspection**

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

Next Inspection Date **2/2008** ( ) Normal (X) Reduced

Justification for reducing the routine inspection interval: **The inspection frequency was reduced due to the number of consultant's findings indicative of poor performance observed during this inspection-violations identified regarding security of RAM, surveys, NCV for eating in RAM areas**

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 3/6/2007
Deborah A. Piskura

Approved _____ Date 3/6/2007
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

No licensing actions were issued since the previous inspection.

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

The last inspection on 1/23/2004 was the license's initial inspection; no violations of NRC requirements were identified.

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 licensee was a hospital (300 beds capacity) authorized to use licensed material permitted by Sections 35.100, 35.200, and 35.500. The nuclear medicine department was staffed with four full-time technologists who performed approximately 120+ diagnostic nuclear medicine procedures per month. The majority of the studies were bone, cardiac, and gall bladder imaging. The department was open daily and on weekends for emergency on-call cases. The licensee received unit doses and bulk Tc-99m from a licensed radiopharmacy.

During this inspection, the inspector toured the nuclear medicine department, interviewed licensee personnel, observed activities in progress, performed radiation surveys around the hot lab, and reviewed select records. The inspector identified two violations and one NCV of NRC requirements during the inspection.

Management Oversight
Dr. Shameen Menon, serves as the Radiation Safety Officer (RSO) and as the authorized physician user. Dr. Menon is on-site monthly and she reviews and signs the consultant's reports and the radiation safety documents. Prior to November 2006, the licensee utilized the services of two contract firms to staff the nuclear medicine department. In August 2006, the hospital appointed a new manager for the nuclear medicine activities. This manager noted several work practices by the contract staff which he found unacceptable and unprofessional; he requested that the executive management authorize him to recruit for in-house technologists. Due to poor findings noted during the consultant's quarterly audits,

billing irregularities, and general performance issues, the hospital terminated its contract with the firm and hired in-house full-time technologists.

The licensee retained the services of a consulting physicist to review its radiation safety program every calendar quarter. The last audit was conducted on Dec. 1, 2006, with several reminders to comply with NRC requirements regarding security, worker instruction, personnel monitoring, record keeping, and rules for the safe use of radiopharmaceuticals; otherwise the consulted noted no unusual findings or identifications of violations of NRC requirements. During the consultant's visits for the months of Jan., Aug., & Oct. 2006, the consultant identified a number of examples of noncompliance with the NRC regulations and license conditions. The consultant had identified occasions where there was evidence of technologists eating in the nuclear medicine hot lab room during his Jan. 18 and Oct. 10, 2006, quarterly audits.

The consultant also found during his Jan. 18, audit that the technologists left the hot lab door open with no one maintaining surveillance of the licensed material located within. During audits in Aug., Oct., & Dec. 2006 the consultant reminded the licensee to secure/maintain constant surveillance of its RAM. According to the department manager, past practices included leaving doses in the cardiac stress areas (on a counter) momentarily just prior to injection. While other staff (nurses, exercise physiologists, physicians) were instructed to maintain surveillance over the doses, the manager disapproved of this practice (Note: this practice would not be in violation of NRC requirements since trained staff, although not NMTs watched over the doses). The manager believed that if the NMTs left these doses, there was a breech in the chain-of-custody. All NMTs were verbally instructed the Fall 2006 to maintain constant surveillance of the doses, especially in the cardiac area.

Additional audit findings identified by the consultant included:
1. Lack of records for package return surveys for the months of Nov.-Dec. 2005(presumed to be lost or misfiled)
2. Failure to perform daily dose calibrator constancy checks for 02/05/2006 and 8/31/2006 (a violation of minor safety significance)
3. Failure to perform daily exposure-rate surveys on 05/13/06, 05/27/06, 07/31/06, 08/01/06, 08/02/06, 08/04/06, 08/05/06, 08/12/06, 0//8/21/06, 09/09/06, and 10/06/2006
4. Failure to perform weekly wipe tests surveys for removable contamination for the weeks of 08/07/06, 08/21/06, 09/05/06 and 9/11/06

These audit findings prompted the inspector to focus on security, surveys, and practices.

Security of RAM

During the afternoon of the inspection, the inspector returned to the hot lab and observed that no other technologists were present in the hot lab (Room 1622) which was located within the camera room (Room 1622). The inspector observed that no other technologists were present in the hot lab (Room 1622) within camera room (Room 1622), although there was a patient on the table in process of a scan. Refer to the attached floor plan depicting the arrangement of the hot lab and the scan room within the radiology department. The inspector waited at the doorway for about three minutes until a staff technologist arrived at the room. Once inside the hot lab, the inspector found unsecured licensed material which included a vial

of bulk technetium-99m (273 millicuries), 180 millicuries of technetium-99m in unit dose form; various microcurie check sources, and millicurie quantities of radioactive waste. According to the technologist, she was sitting at the computer console and keeping watch over the hot lab. The technologist explained that due to a patient emergency in the other camera room (Room 1619), she was called by other staff technologists to assist with that patient. She understood from the urgency of their call that they required immediate assistance with the patient and quickly exited the room without first closing the hot lab door. Best estimates, the technologist was out of the room for approximately 5 minutes. Patients and transporters were also in the hallway at this time.

The licensee implemented immediate corrective action by securing the hot lab door and/or maintaining constant surveillance. The licensee will consider installing a self-closing mechanism on the hot lab door. The licensee also retrained all department staff in security and control of licensed material. One violation of NRC requirements was identified (10 CFR 20.1801/20.1802).

Rules for Safe Use of Radiopharmaceuticals

The consultant identified two occasions where contract technologists were eating in the hot lab/camera room (a violation of the licensee's procedures for safe use of radiopharmaceuticals and License Condition 16). During his Jan. 18, 2006, visit, the consultant found a technologist's handbag which contained a banana and an orange, stored within the nuclear medicine hot lab. The consultant had also found evidence of eating in the nuclear medicine hot lab or camera room (cracker wrappers found in the hot lab trash can) during his 10/10/2006 quarterly audit. According to the department manager and the RSO, these habits were highly frowned upon and the staff were re-trained on the hospital's policies and procedures (No.1646.05, "Procedure for Safe Use of Radiopharmaceuticals,") prohibiting eating and drinking in areas where radioactive materials are used and stored. Since the licensee hired in-house, staff technologists, no additional instances or evidence of food consumption within the hot lab or the camera rooms has been identified. The licensee believed this was an isolated occurrence. The inspector discussed this matter with the technologists who confirmed that they only consumed food and drink in the break room and not in the restricted areas within the department. Since this violation was identified during the consulting physicist's audits, the licensee took corrective actions, and the issue appeared to be isolated, the violation will be characterized as a non-cited violation in accordance with the Enforcement Policy.

Surveys

During the inspector's review of the consultant's audit reports, she noted several instances, as mentioned above, where package surveys, daily exposure-rate surveys, and weekly wipe tests were apparently not being performed by the technologists at the required frequencies. The inspector also reviewed survey records for the months of Nov., Dec., and Jan. 2007 and found that the staff had failed to perform daily surveys and weekly wipe tests on numerous occasions. During the month of Nov. 2006, the licensee failed to perform daily surveys on 11/3, 11/6, 11/7, 11/16, 11/17, 11/22, 11/27, 11/28 and 11/29. The inspector noted that for the entire month of Dec. 2006, the licensee only performed daily surveys on three occasions: 12/8 12/22, and 12/27. For the month of Dec. 2006 the licensee only performed weekly wipe tests on two occasions (missing weekly wipe tests for the weeks ending 12/1, 12/15, and 12/29. During Jan. 2007, the licensee missed

area surveys for 1/2, 1/5, 1/8, 1/9, and 1/22. The weekly wipe tests for the week ending 1/5 was also not performed.

The inspector discussed this matter with the nuclear medicine personnel at length. The technologist scheduled for the "late shift" was expected to perform these surveys, however the staff could not offer an explanation as to the reason the surveys and wipes were not being performed. The licensee committed to perform the required surveys and planned to develop a mechanism to remind the staff to perform the surveys.

The inspector inquired about any incidents or spills which may occurred while the current staff worked at the hospital. The licensee staff described two contamination incidents in the Fall involving a former contract technologist's shoe and an article of clothing worn by an exercise physiologist. Both incidents involved a small quantity (a droplet of Tc-99m) of contamination, most likely from a procedure in the cardiac treadmill room. One technologist witnessed and recalled that the a former technologist wrote up a spill report for one of these incidents, however no one could locate this spill report in the records. The staff also recalled the former technologist's recorded survey results in the treadmill room as "200 mR", and provided the survey results to the inspector. No additional notations were in these records (decontamination efforts, additional surveys of the area after decontamination attempts, special postings, etc.). The staff believed these survey results were highly inaccurate given the presumably small quantity of Tc-99m involved in the incidents. Further, the licensee's surveys of the same area the next morning were at background. No additional contamination of the adjacent areas, hallways, etc. was identified by the staff. According to the technologists and the RSO, to their knowledge, no additional spills, and specifically no major spills have occurred during 2006.

2. INSPECTION SCOPE

INSPECTION PROCEDURE(S) USED: **87130**

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)

A side-by-side comparison of the licensee's survey instruments and the inspector's instrument was made with a 1 μCi Cs-137 check source. All instruments were within 20% agreement. 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 L-block, 0.8 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.

A. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on January 31, 2007, the licensee did not secure from unauthorized removal or limit access to: (1) 180 millicuries of technetium-99m in unit dose form; (2) 273 millicuries of bulk Tc-99m; (3) millicurie quantities of radioactive waste and (4) various check sources of microcurie activity, located within the hot laboratory of the Nuclear Medicine Department, which is a controlled area. Specifically, a nuclear medicine technologist exited the hot laboratory and adjacent camera room to attend to a patient and failed to close the hot laboratory door, leaving the licensed material unsecured.

B. Condition 14.A. of License No. 21-32449-01 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application, dated February 24, 2003, with attachments.

Item 10, "Radiation Protection Program," of the application, dated February 24, 2003, states that the licensee has developed and will implement written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

1. **Section 4 of Licensee Policy 1645.13, "End of Day Surveying and Meter Usage," dated June 21, 2006, developed in accordance with Item 10 of the licensee's application, requires in part, that surveys be routinely done at the end of each working day in the hot lab, in the camera rooms, clinical areas, patient injection areas, and in the stress lab area.**
2. **Section 1.1.2 of Licensee Policy 1645.14 "Weekly Wipe Testing," dated June 21, 2006, developed in accordance with Item 10 of the licensee's application, requires, in part, that weekly wipes be performed in all designated areas, such as the Hot Lab, imaging area, and the stress lab.**

Contrary to the above, on numerous occasions between November 2006 and January 2007:

1. **The licensee did not perform surveys at the end of each working day in the hot lab, in the camera rooms, clinical areas, patient injection areas, and in the stress lab area.**
2. **The licensee did not perform weekly wipes in all designated areas, such as the Hot Lab, imaging area, and the stress lab.**

Non-cited violation

Condition 14.A. of License No. 21-32449-01 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in application dated February 24, 2003.

Item 10, "Radiation Protection Program" of the application, dated February 24, 2003, states that the licensee has developed and will implement written procedures for safe use of unsealed byproduct material that will meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301references that the licensee developed and will implement procedures for the safe use of unsealed byproduct material that meets the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

Item 4. of licensee policy 1646.05, "Procedure for Safe Use of Radiopharmaceuticals," dated June 21, 2006, requires, in part, that eating, drinking, smoking or applying cosmetics is not permitted in areas where radioactive materials are stored or used. Food, drink, or personal belongings can not be stored in radioactive areas.

Contrary to the above, during the consulting physicist's January 18, 2006 audit, a nuclear medicine technologist's handbag containing an orange and a banana, was stored within the licensee's hot lab, an area where radioactive materials are stored and used. In addition, the consulting physicist identified evidence of eating (cracker wrappers in the trash can) in the hot lab during his October 10, 2006, audit.

5. PERSONNEL CONTACTED:

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

***Diane Pressley-Capers, Vice President, Professional Services**
+Shameem Menon, M.D., RSO & Authorized User
***Mark Bradford, RN, BHSA, Manager, Cardiology/Neurology Services**
***#Michael Bearss, RT(R), RT(N), CNMT, Lead Technologist**
Scott Rettig, CNMT
Laura Meyers, CNMT, Maxium
Jack Zeller, CNMT
Sarah Miller, Exercise Physiologist

+Kevin Miller, Consultant

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