

## INSPECTION RECORD

Region III Inspection Report No. 030-36996/10-01

License No. 13-32585-01 Docket No. 030-36996

**Licensee (Name and Address):**

Cardiac Care Consultants  
1730 45<sup>th</sup> Street  
Munster, Indiana 46321

**Location (Authorized Site) Being Inspected:** 1730 45th Street. Munster, Indiana 46321

**Licensee Contact:** Dr. Anuradha Divakaruni – RSO **Telephone No.** (219) 836-9677

**Priority:** 5 **Program Code:** 2201

**Date of Last Inspection:** 4/10/2006 **Date of This Inspection:** 9/23/2010

With continued in-office review until 10/7/10 to  
review records related to previous location of use


**Type of Inspection:** ☐ Initial ☐ Announced ☒ Unannounced  
☒ Routine ☐ Special

**Next Inspection Date:** 9/2015 ☒ Normal ☐ Reduced

**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
- ☒ Violation(s), regional letter issued
- ☐ Follow-up on previous violations

Inspector

  
Andrew M. Bramnik, Health Physicist

Date

11/5/2010

Approved

  
Tamara E. Bloomer, Chief, Materials Inspection Branch

Date

11/5/10

Enclosure

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

### **1. AMENDMENTS AND PROGRAM CHANGES:**

<u>Amendment No.</u>	<u>Date</u>	<u>Subject</u>
4	10/2/2009	New RSO (Dr. A. Divakaruni) and New Location of Use authorized (1730 45 <sup>th</sup> St., Munster, IN)
3	2/11/2008	New Authorized Users authorized
2	7/3/2007	Removal of Previous Location of Use from License (9120 Columbia Ave., Munster, IN)
1	3/2/2007	New Location of Use authorized (9124 Columbia Ave., Munster, IN)
0	9/2/2005	New License Issued

### **2. INSPECTION AND ENFORCEMENT HISTORY:**

No violations were identified during the last inspection on April 10, 2006. The April 2006 inspection was the initial inspection for this licensee.

### **3. INCIDENT/EVENT HISTORY:**

None

## **PART II - INSPECTION DOCUMENTATION**

### **1. ORGANIZATION AND SCOPE OF PROGRAM:**

#### **Organizational Structure:**

Dr. Shashi Divakaruni – Owner and Authorized User (AU)  
Dr. Anuradha Divakaruni – Radiation Safety Officer (RSO) and AU  
One Nuclear Medicine Technologist reported to Dr. A. Divakaruni

The licensee operated a private cardiac clinic in Munster, Indiana, and was authorized to possess and use any byproduct material permitted by Title 10 of the Code of Federal Regulations (10 CFR) Part 35.200. One full-time nuclear medicine technologist performed all patient procedures. The licensee obtained licensed material as unit doses from an area nuclear pharmacy, and did not use xenon-133 or molybdenum/technetium generators. The licensee performed cardiac scans, as well as an occasional MUGA scan. The licensee was not authorized to perform or administer therapeutic doses.

### **2. SCOPE OF INSPECTION:**

Inspection Procedure(s) Used: 87130

Focus Areas Evaluated: Sections 03.01 through 03.07

Interviews conducted with available staff revealed an adequate level of understanding of emergency and material handling procedures and techniques. Dose calibrator constancy checks, package receipt, daily surveys, and waste handling and disposal procedures were successfully demonstrated or observed. An outside consultant performed quarterly program audits that appear to adequately oversee licensed activities.

Personal whole body and extremity dosimetry was observed being worn by the staff during the inspection. Dosimetry records indicated maximum whole body and extremity readings for 2009 of 460 mrem and 1930 mrem, respectively. The 2010 year-to-date whole body and extremity readings were 98 mrem and 250 mrem, respectively.

### **3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:**

The licensee's survey meter was found to be calibrated and operational, and performed well in side-by-side comparison with an NRC survey meter. Independent measurements taken did not indicate readings in excess of 10 CFR Part 20 limits in restricted or unrestricted areas.

4. **VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:**

- A. Title 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 September 23, 2010, the licensee did not secure from unauthorized removal or limit access to one cobalt-57 flood source, one barium-133 reference source, and several cesium-137 reference sources located in the hot lab, which is a controlled area. Specifically, the doors to the hot lab were unlocked, open, and not under surveillance by any authorized person to prevent access for several minutes when the inspectors arrived.

The root cause of this violation was inattentiveness on the part of the nuclear medicine technologist when the NRC inspector arrived at the facility. Upon escorting the inspector to the hot lab, the technologist had left both doors to the hot lab unlocked and open; one of the doors lead to a waiting area where patients were sitting, and one of the doors lead into the main section of the facility.

As immediate corrective actions, on September 24, 2010, the RSO reinforced the requirement for effective measures to secure licensed materials with the technologist. To prevent recurrence, the licensee committed to supplement existing automatic keypad locks currently installed on the hot lab doors by installing hydraulic, automatic-closing hinges. During a telephone conversation on November 5, 2010, the nuclear medicine technologist stated that these actions would not be complete until November 30, 2010.

- B. Title 10 CFR 30.36(d) requires, in part, that licensees provide notification to the NRC in writing within 60 days of any of the following occurrences:

1. The license has expired;
2. The licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements;
3. No principal activities under the license have been conducted for a period of 24 months; or
4. No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements;

Contrary to the above, as of June 7, 2010, the licensee decided to permanently cease principal activities at the entire site located at 9124 Columbia Avenue, Munster, Indiana, and the licensee failed to notify the NRC in writing within 60 days of this occurrence. Specifically, the licensee did not notify the NRC of this occurrence until October 4, 2010.

The root cause of this violation was the licensee's lack of awareness of the need to ensure that the information listed on their license was current. Although the licensee's physicist had conducted close-out surveys on June 7, 2010, at 9124 Columbia Ave., Munster, Indiana, neither the results of these surveys nor written notification of the licensee's decision to cease principal activities at this address were received by the NRC within 60 days thereafter.

As corrective actions, the licensee faxed the results of these surveys to the NRC on October 4, 2010. In the facsimile to the NRC, the licensee stated that all radioactive materials were transferred to the current location at 1730 45<sup>th</sup> Street, Munster, Indiana. As long term corrective actions the licensee is now aware of the requirements, and on October 7, 2010, the licensee informed the NRC that they do not anticipate changing addresses in the near future.

5. **PERSONNEL CONTACTED:**

\*& Dr. Anuradha Divakaruni, RSO

Use the following identification symbols:

\* Individual(s) present at September 23, 2010 preliminary on-site exit meeting

& Individual(s) present at October 7, 2010 telephone exit meeting

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