



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

1. AMENDMENTS AND PROGRAM CHANGES:

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
5	2/15/2013	License renewal
4	4/23/2010	Removed Hamtramck location of use
3	3/17/2010	Replaced RSO and authorized user

2. INSPECTION AND ENFORCEMENT HISTORY:

The NRC conducted a reactive inspection of this licensee on 3/16/2010 to review the circumstances surrounding a letter dated 2/26/2010 requesting to remove the RSO from the license. Two Severity Level IV violations were identified during this inspection, one for failure to appoint a replacement RSO and another for failure to notify the NRC within 30 days that an authorized user had permanently discontinued the performance of his duties. These violations were not found to be recurring, and based on a review of corrective actions documented in NRC Inspection Report 030-36030/10-01(DNMS) these items are now considered to be closed.

The last routine inspections were on 6/3/2008 and 8/11/2003. No violations of NRC requirements were identified during either inspection.

On 12/28/2010, the NRC issued this licensee an order revoking the license within 30 days based on the nonpayment of license fees. The order was eventually withdrawn.

3. INCIDENT/EVENT HISTORY:

None

**PART II - INSPECTION DOCUMENTATION**

1. ORGANIZATION AND SCOPE OF PROGRAM

This licensee is a cardiac clinic authorized by NRC License Number 21-32401-01 to use unsealed byproduct material for diagnostic procedures under 10 CFR 35.200 at its office in Oak Park, Michigan. The clinic is open Tuesdays, Thursdays and Saturdays. However, the clinic has not performed any diagnostic nuclear procedures in over two years, and as such does not currently have a nuclear medicine technologist on staff. Instead, the clinic retained the services of a medical physics consultant to perform the duties of the RSO. At present, the consultant performs instrument calibrations, leak tests, inventories and audits.

2. SCOPE OF INSPECTION

Inspection Procedure(s) Used: 87130

Focus Areas Evaluated: 1-7

The inspector toured the disused nuclear medicine lab and interviewed the president and contract RSO. The inspector also reviewed a selection of licensee records, including those for instrument calibrations, leak testing, inventories and audits.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS

Using a Ludlum 2403 survey meter with a model 44-38 energy-compensated GM detector calibrated January 16, 2013, the inspector surveyed the hot lab and imaging room to verify compliance with posting requirements and public dose limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

A. Security of Licensed Material

On April 16, 2013, the inspector identified a violation of 10 CFR 20.1801 for failure to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. The inspector noted that the door from the lobby and the door to the hot lab were not locked, and that the area between these doors was not under constant surveillance of licensee personnel. The hot lab contained two Co-57 flood sources and four Cs-137 and two Ba-133 reference sources. The attending staff indicated that the door to the hot lab was left unlocked because for some time they have been unable to locate the key to the door.

The room was set aside exclusively for nuclear medicine procedures; therefore the licensee restored compliance by locking and closing the hot lab door, even though they could not locate the key to reopen it while the inspector was on-site.

The licensee's contract RSO indicated to the inspector that he would attempt to retrieve the remaining licensed material from Dr. Raval's hot lab within a week of the NRC inspection. On May 10, 2013, the RSO notified the inspector that May 7, 2013, the sources had been successfully transferred to Radiological Physics Services (NRC License Number 21-26253-01), and on May 24, 2013, the RSO provided verification of the transfer.

B. License Termination

On April 17, 2013, during a review of audit records that had not been available while on-site, the inspector identified a violation of 10 CFR 30.36(d) for failure to provide notification to the NRC in writing that no principle activities had been conducted under the license for a period of 24 months, and for failure to begin decommissioning or request an extension under 10 CFR 30.36(f). The inspector noted that the RSO's March 2011 audit stated that "no patient studies were performed during the last two inspections." Subsequent audits in June 2011 (the last audit at a quarterly frequency) and in May 2012 (the first at an annual frequency) made similar statements. The audit prior to March 2011 was conducted in December 2010; therefore, no principal activities had been conducted for a period of at least 27 months as of April 17, 2013.

The RSO stated during the exit meeting that Dr. Raval wished to retain his license and resume principal activities at a later date, and therefore as a corrective action the RSO committed to sending a letter to the NRC requesting that the license be put in standby until the licensee was ready to resume the conduct of principal activities, at which time the RSO would request a license amendment to return the license to an active status. The RSO provided an unsigned copy of the request to the inspector on May 24, 2013.

5. PERSONNEL CONTACTED:

\*^ Ray Carlson, M.S., RSO – Radiological Physics Service  
Pramod Raval, M.D., Licensee – Pramod Raval, M.D., P.C.

\* Individual(s) present at the preliminary telephonic exit meeting on April 16, 2013

^ Individual(s) present at the final telephonic exit meeting on May 17, 2013

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