

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

1. AMENDMENTS AND PROGRAM CHANGES:

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
06	06/25/2013	designated 5451 Hampton Place, Saginaw, MI, as an authorized location of use
05	06/05/2013	added 8273 S. Saginaw, Grand Blanc, MI, an authorized location of use
04	09/03/2010	mailing address change*
03	05/07/2010	new location of material receipt and use

*see Part II Item 1

2. INSPECTION AND ENFORCEMENT HISTORY:

No violations of NRC regulatory requirements were cited during previous inspections conducted on February 22, 2010, (routine) and May 19, 2006 (initial).

3. INCIDENT/EVENT HISTORY:

None.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

This licensee was a private practice multidiscipline clinic, operating a mobile nuclear medicine service, and authorized to use licensed material permitted by Section 35.200. According to License Condition 10., the licensee was authorized to use and store licensed material at its facilities located in Burton and Traverse City, Michigan. The licensee was also authorized to receive doses at its mobile van located in Saginaw, Michigan. None of the locations listed maintained a hot lab; all doses were delivered to the mobile van. The clinic employed two technologists who performed 70-100 patient studies each month. The licensee received unit doses from a licensed radiopharmacy. The licensee relied on the pharmacy's assay or corrected for decay. The licensee retained a consultant who audited the radiation safety program on a quarterly basis (last audit on 3/29/2013, with no findings).

This inspection consisted of interviews with licensee personnel, a review of selected records, a tour of the nuclear medicine department, and independent measurements. On the day of the inspection, no cardiology studies were performed.

Discussions with the licensee personnel revealed that the licensee performed cardiac studies involving radioactive material at its Grand Blanc business address listed in Item 2. of their license. The radiopharmacy (CPI Pharmacy d/b/a HOTSHOTS, Lic. No. 21-26597-01MD) delivered doses to the van parked in the lot behind the business. The

inspector noted that this Grand Blanc address was not specifically listed as an authorized location of use in License Condition 10. According to the licensee they had been performing cardiac studies at least weekly since 2010. A review of the use and survey records confirmed that cardiac studies had been performed at the Grand Blanc office.

In its letter dated August 13, 2010 (ML102310333), the license submitted an amendment request to change its "fixed address" to 8273 S. Saginaw, Grand Blanc, Michigan. The licensee's letter stated that the site was to be used for storing imaging equipment and specified no radioactive sources or waste would be stored at this site. The licensee's letter stated that RAM would be received at the van (parked at the building). Although the licensee included a floor plan of their new facility, they emphasized that this location was a business address. Therefore, the licensee was in violation of License Condition 10, since it administered doses and imaged patients at this address which was not specifically listed on the license as an authorized location of use. The root causes of this violation was attributed to the licensee staff's misunderstanding of the terms of its license and the conflicting language used by the licensee's consultant in the amendment request for this location. The inspector explained the terms and conditions of the license (specific to Items 2. and Condition 10.) to licensee management.

On June 3, 2013, the Materials Licensing Branch (MLB) received a call from the licensee inquiring about its location in Saginaw, Michigan. The licensee read the recent license amendment (No. 05, ML13157A196) and noted that the location at 5451 Hampton Place, Saginaw, Michigan, was not listed as an authorized location of use; the staff informed MLB (who in turn informed the inspector) that they administered patient doses at this location since 2010. The licensee committed to file an amendment request as soon as possible to expand the authorization of the Saginaw clinic as an authorized location of use. On June 25, 2013, MLB issued amendment No. 06, authorizing this Hampton Place clinic as a location of use.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87130

Focus Areas Evaluated: 03.01 - 03.08

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Survey Instrument Used: Canberra UltraRadiac, NRC Tag No. 33536G
Calibration Date: 01/16/2013

The inspector performed direct radiation measurements in and around the licensee's mobile van and storage and imaging areas within the Grand Blanc office. The inspector also performed direct radiation measurements on June 18, 2013, around the licensee's imaging and injection areas within the Saginaw office. All radiation levels were indistinguishable from background. All survey measurements were comparable to the licensee's survey results.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

One violation of NRC requirements was identified during this inspection:

10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct material to the locations and purposes authorized by the license.

Condition 10. Of NRC License Number 21-32601-01 states, in part, that licensed material may be used or stored at the licensee's facilities located at specific locations in the State of Michigan.

Contrary to the above, from approximately September 2011 through May 2013, the licensee did not confine its possession and use of byproduct material to the locations authorized by the license. Specifically, the licensee received and used byproduct material at the licensee's office located at 8273 S. Saginaw, Grand Blanc, Michigan, a location not authorized by the license. Additionally, from October 11, 2010, through May 2013, the licensee also used byproduct material at its office located at 5451 Hampton Place, Saginaw, Michigan, a location only authorized for receipt and storage of licensed material.

The licensee submitted an amendment request to the region via FAX on May 15, 2013. The inspector discussed her inspection findings with Dennis O'Dowd, License Reviewer. On June 5, 2013, MLB issued Amendment No. 05, authorizing the Grand Blanc, Michigan, clinic as a location of use. On June 7, 2013 the licensee reviewed its Amendment no. 05. The NMT contacted MLB reviewer and noted that its location at 5451 Hampton Place, Saginaw, Michigan, was listed as a location where byproduct material may be received and stored however the licensee also performed cardiac studies at this clinic. According to the NMT, the licensee administered cardiology studies at least monthly since October 11, 2010, at this location and the clinic should be specifically authorized as a location of use. The licensee verbally committed to halt use at this location until it received an amendment from the NRC. The licensee submitted a second amendment request on June 12, 2013, to expand the authorization for the 5451 Hampton Place, Saginaw, Michigan clinic as a location of use.

5. PERSONNEL CONTACTED:

+Zakwan Aboudane, President
*#Darlene Young, CNMT
*#Suzanne Itani, Office Manager
+Anthony Bennett, M.D., RSO

Use the following identification symbols:

Individual(s) present at entrance meeting
* Individual(s) present at exit meeting
+Individual contacted by telephone