

August 13, 2013

License No. 21-32601-01

U.S. Nuclear Regulatory Commission Region III
Materials Licensing Branch
2443 Warrenville Road, Ste. 210
Lisle, IL. 60532-4352

RE: "Reply to a Notice of Violation"

Att: Regional Administrator

Dear Sir/Madame:

In accordance with the NRC Enforcement Policy, one violation is listed below:

Title 10 of the Code of Federal Regulations (CFR) Part 30.34 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 License No. 21-32601-01 states, in part, that licensed material may be used or stored at the licensee's facilities located at specified locations within the state of Michigan.

Licensee received and used byproduct material at the licensee's office at 8273 S. Saginaw, Grand Blanc, Michigan, a location not authorized by the license.

Licensee used byproduct material at its office located at 5451 Hampton Place, Saginaw, Michigan, a location only authorized for receipt and storage of licensed material.

On May 15, 2013, a NRC inspection was conducted. It was noted under Condition 10 of License No. 21-32601-01 that the offices of the licensee were not stated properly for use, storage and receipt of byproduct material. Letters dated April 6, 2010 and August 13, 2010 were reviewed. The intentions of Conditions discussed between the lead Nuclear Medicine Tech. and the Physicist were misinterpreted. In reference to letter dated, April 6, 2010, under Amendment No. 3, a request was made to add an additional site: 5451 Hampton Place, Saginaw, Michigan. It was stated in the license to **receive and store** licensed material only, when in fact the request should have been for **use, storage and receipt**. Upon receipt of Amendment No.3, it was not reviewed by our physicist or lead Nuclear Medicine Tech. for the overall objectives and requirements to be clearly stated and implemented.

The August 13, 2010 letter, requested 8273 S. Saginaw, Grand Blanc, Michigan to be added as a fixed business address for License No. 21-32601-01. In addition, the intention was to use it for **use, storage and receipt** of licensed material. (**Use** as one of our mobile addresses and it will be surveyed and wiped after each use. Radioactive pkgs. will be **received** on the van. All radioactive materials **stored** in the locked van.) The wording of the intentions needed, were not stated clearly. The NRC reviewer probably should have contacted the physicist with any questions. Upon receipt of Amendment No. 4, it was not

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reviewed by our physicist or lead Nuclear Medicine Tech. for the overall objectives and requirements to be clearly stated and implemented.

On May 15, 2013, a phone conversation with the NRC Inspector and Physicist took place. They reviewed the interpretation and intent of letters dated April 6, 2010 and August 13, 2010. The two sites (Grand Blanc and Saginaw offices) are fixed sites owned by Mid-Michigan Diagnostic and cannot be treated as mobile sites.

After reviewing the letters and misinterpretations implied, we took a same day corrective action. A letter dated May 15, 2013 was faxed to the NRC Material Licensing Branch for an amendment to the license for location revisions for licensed material **use, storage and receipt** (Condition 10) and to add 8273 S. Saginaw, Grand Blanc, Michigan. Keep 5451 Hampton Place, Saginaw, Michigan.

A phone conversation with the NRC Reviewer and our lead Nuclear Medicine Tech took place a few days later. There was a discussion on asking for an expedited review for reason of patient care and scheduling at our locations. The reviewer also suggested a statement in the letter to address Public Health and Safety. A follow-up letter dated June 4, 2013 was faxed to the NRC, stating our intentions.

On June 6, 2013, Amendment No. 5 was sent by the reviewer via email to the lead Nuclear Medicine Tech for review. After review of the Amendment No. 5, the tech had a phone conversation with the reviewer about Condition 10. Licensed material may be **used or stored** only at licensee's facilities at 8273 S. Saginaw, Grand Blanc, Michigan and may be **received and stored** at 5451 Hampton Place, Saginaw, Michigan. The tech questioned the wording was different for each office. In reference to letter dated May 15, 2013, it stated licensed material **use, storage and receipt (Condition 10)**. There was confusion on adding the Grand Blanc office, and the reviewer overlooked the wording for Condition 10.

A new letter dated June 12, 2013 was faxed to the NRC to amend the license for 5451 Hampton Place, Saginaw, Michigan so that licensed material may be **used or stored** at the Saginaw location. In regards to the Saginaw office, the NRC Inspector had a phone conversation with the lead Nuclear Medicine Tech to state there would be an inspection of 5451 Hampton Place, Saginaw, Michigan. On a surprise visit on June 18, 2013 a floor plan was provided for her to see the location of rooms to be used for patient imaging.

On June 25, 2013, Amendment No. 6 showed the correction: Licensed material may be **used or stored** at the licensee's facilities located at 8273 S. Saginaw, Grand Blanc, Michigan and at 5451 Hampton Place, Saginaw, Michigan. The Amendment was reviewed by our physicist and lead Nuclear Medicine Tech.

Full compliance was achieved on June 25, 2013, with NRC in-office review. A final exit meeting occurred with the NRC Inspector and Office Manager – Mid-Michigan Diagnostic per telephone conversation on June 28, 2013.

In summary, prompt action was taken to correct the License no. 21-32601-01 Mid-Michigan Diagnostic.

1. May 15, 2013 – NRC Inspection showed violation on use, storage and receipt of licensed material. Suggestion of a locked door on stress room at Grand Blanc office. Door lock installed May 16, 2013 to secure patient doses during testing, and or technical surveillance at all times.
2. May 15, 2013 – Letter sent to NRC same day to amend license.
3. Continual conversations between NRC Inspector and NRC Reviewer.
4. Consultation of our physicist for review of past letters and formation of new letters.
5. June 4, 2013 – Letter to NRC for expedited review; Address Public Health and Safety in regards to use and receipt ; Constant Surveillance
6. June 6, 2013 – Amendment No. 5 received. A hold was placed on patient scheduling at Grand Blanc and Saginaw offices until license corrected. Delivery of licensed materials for mobile accounts, were placed in locked van, at Saginaw office only, until license corrected.
7. June 12, 2013 – Amendment for Hampton Place, Saginaw, Michigan for licensed material to be used or stored at that location.
8. June 25, 2013 – Amendment No. 6 received.
9. June 28, 2013 – Final exit meeting.

Steps taken for Prevention of Recurrence of Violation:

1. All licensing requests will be reviewed by: Physicist, lead Nuclear Medicine Tech. and Management at Mid-Michigan Diagnostic.
2. Safety concerns addressed: use and receipt of doses by Nuclear Medicine Tech; locked van for doses and sources; doses under surveillance at all times; locked stress room door at Grand Blanc office for patient scheduling.
3. Organizational Changes: New lead Nuclear Medicine Tech; Physicist Group: changed to a different member in the group; Office Manager will be informed of changes and given copies of all documents.
4. There will be copies of all letters to the NRC, with updates and availability of the files.
5. Staff members notified of violation and corrective action taken.
6. System in place to keep up with new or modified NRC requirements regarding our license.

In summary, the initial letters dating April 6, 2010 and August 13, 2010, showed the application and intent to amend our license, for the two locations of Grand Blanc and Saginaw. The wording and interpretation of our intent were not stated clearly or interpreted correctly. We feel we took immediate corrective action upon the discovery of errors, in a timely manner. Please consider this a positive approach in achieving the necessary objectives and requirements needed. Our new organizational changes of staff will prevent future errors as well.

Sincerely,

A handwritten signature in black ink, appearing to read "Zakwan Aboudane". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Zakwan Aboudane, President
Mid-Michigan Diagnostic