



**FACSIMILE COVER PAGE**

Date: 22 May 2017

To: US Nuclear Regulatory Commission  
Region III  
Attn: Ms. Cassandra Frazier

Fax #: 630.515.1078

# pages (incl cover): 3

From: Tom Ludlam  
President/CEO  
Molecular Imaging, Inc. d/b/a MI BioResearch

Subject: **Status of Amendment #12 - NRC License 21-32816-01**

Dear Ms. Frazier:

On 10 March, 2017, Molecular Imaging, Inc., doing business as MI BioResearch, sent a letter to NRC regarding a desired amendment to the above referenced license. The amendment requested removal of an Authorized User who had left our employ and addition of the use of unsealed sources of Iodine-131. For convenience, I have attached that amendment to this fax.

On 30 March, 2017, the NRC confirmed receipt of same and noted that the preliminary review indicated no administrative omissions.

While we realize that NRC has only had the amendment under review for 6-7 weeks, it would be appreciated one of your team could advise as to the status of the review and possible timeline for receiving initial guidance. MI BioResearch is a service provider to pharmaceutical and biotechnology companies. We have a client eager to start preclinical studies using Iodine-131 and would like to provide some update for their planning purposes.

Thank you in advance for any information you can provide. I can be reached at any of the following:

Office #: 734.926.4200  
Cell #: 614.403.3253  
Email: [tludlam@mibioresearch.com](mailto:tludlam@mibioresearch.com)

Sincerely,

Tom Ludlam  
President/CEO



US Nuclear Regulatory Commission, Region III  
 Materials Licensing Branch  
 2443 Warrenville Rd. Suite 210  
 Lisle, Illinois 60532-4352

March 10, 2017

Licensee: Molecular Imaging, Inc. dba MI BioResearch (MI)  
 Address: 800 Technology Drive, Ann Arbor, MI 48108  
 License #: 21-32816-01, Amendment #12  
 Action: **Amendment Request to Add Type of Use and Remove Authorized User (AU)**

Dear Sir or Madam,

Please accept this letter as a request to amend our radioactive materials license no. 21-32816-01 with an additional unsealed material, and to remove an AU.

First, please remove authorized user Deanne Lister.

Second, please add authorization for unsealed sources of Iodine-131. We intend to perform therapeutic research procedures on rats and mice on an approximately bimonthly basis.

Below, please find information about the proposed additional material and its use corresponding to items 5, 6, 8, 9, 10, and 11 of NRC Form 313:

5a) Element	5b) Physical Form	5c Max. Amt.	6) Intended use
Iodine-131	Unsealed	200 $\mu$ Ci per dose, 125 mCi total	For research and development as defined in 10 CFR 30.4 in rodents  (Therapeutic studies, no imaging)
	Bound		
	In chelate compounds		

8) Our current training program has not changed significantly since previously submitted; we believe no modifications to this are necessary in order to use Iodine-131.

9) We believe no modifications are necessary to our facilities and equipment in order to use Iodine-131. As previously stated in our letter dated March 11, 2013, we use 1/4" of Plexiglas in our waste containers, sharps containers, lead-lined freezers, and L-blocks to shield against beta emissions from Ga-68 and Lu-177; this will be sufficient for I-131 as well.



10) We believe no modifications are necessary to our radiation safety program in order to use Iodine-131:

- As the individual doses to be used are relatively small (< 1 mCi), and the opportunity for inhalation will be low, we do not believe that we need to institute a thyroid bioassay nor a urinalysis requirement
- Our current G-M radiation survey meters are sufficient to detect I-131
- Our current radiation monitoring provider states that its badges can detect beta radiation
- Our current survey procedure is sufficient to detect I-131 contamination

11) As with the rest of our unsealed radioisotopes, we will decay it in storage for 10 half-lives before disposal in regular trash. As such, our possession limit must be significantly higher than the individual dose amount, as 10 half-lives of Iodine-131 is approximately 80 days.

As an urgent request for research involving Iodine-131 has been made of us, we would very much appreciate it if this amendment request could be completed as soon as practicable.

Best regards,

A handwritten signature in cursive script that reads "John A. Harvey".

John Harvey, Ph.D., CHP, DABR  
Senior Health & Medical Physicist, West Physics  
RSO, Molecular Imaging Inc. dba MI Bioresearch

On behalf of the management of MI Bioresearch, I hereby attest to and agree to the above. Should you require any additional information in order to process this license action, please do not hesitate to contact me at (734)926-4867

Scott Wise, VP Operations

A handwritten signature in cursive script that reads "Scott Wise" followed by the date "3/10/2017".

CC:

Tom Ludlam  
President and CEO

Enclosure

# FAX

**Date** 05/22/2017

**Number of pages including cover sheet:** 4

**To:** \_\_\_\_\_  
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 \_\_\_\_\_

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**Fax Phone** (630) 515-1078

**From:** \_\_\_\_\_  
 MIR Admin  
 MI Bioresearch  
 800 Technology Dr  
 Ann Arbor MI  
 48108

**Phone** 17349296399

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**REMARKS:**

Re NRC License #21-32816-01 Amendment #12 Status Request