

Date March 28, 2019

To US Nuclear Regulatory Commission, Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4352

From Steve Smith, Director, Environmental, Health and Safety, US and Europe
John Harvey, Ph.D., CHP, Radiation Safety Officer
Molecular Imaging, Inc.
DBA MI Bioresearch
800 Technology Drive
Ann Arbor, MI 48108

Subject Request for Transfer of Control of Radioactive Materials License No. 21-32816-01

To whom it may concern,

This letter is to inform you that on March 7th, 2019 Covance Laboratories Inc. entered into an agreement to acquire Molecular Imaging, Inc. DBA MI Bioresearch with a close date of March 07, 2019. As a result, we are respectfully requesting a transfer of control for Radioactive Materials License No. 21-32816-01 and have provided the following *Information Needed for Transfer of Control* contained within NUREG-1556 Vol. 15, Rev. 1 for your review.

Item No: 1

Describe any planned changes in the organization, including but not limited to, transfer of stocks or assets and mergers, change in members on Board of Directors, etc. Provide the new licensee name, mailing address, and contact information, including phone numbers. Clearly identify when the amendment request is due to a name change only.

Response:

On March 07, 2019, Covance Laboratories Inc. acquired Molecular Imaging Inc DbA MI Bioresearch in a stock purchase deal. There are no planned changes to the organization and it will continue to operate as Molecular Imaging, Inc. DBA MI Bioresearch.

Item No: 2

Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel and any changes in the training program.

Response:

John Harvey, Ph.D., CHP will continue to perform the duties of Radiation Safety Officer. Licensed materials will continue to be used by, or under the supervision of, Sarah Krueger, Ph.D. and Kevin Guley.

Item No: 3

Describe any changes in the location, facilities, equipment, radiation safety program, use, possession, waste management, or other procedures that relate to the licensed program.

Response:

There will be no changes to the location, facility, equipment, radiation safety program, use, possession, waste management, or other procedures that relate to the licensed program as a result of this acquisition.

Item No: 4

Describe the status of the licensee's facilities, equipment, and radiation safety program, including any known contamination and whether decontamination will occur prior to transfer. Include the status of calibrations, leak tests, area surveys, wipe tests, training, quality control, and related records.

Response:

The acquisition of MI Bioresearch will result in no changes to the current status of the radiation safety program. The facility will continue to operate as it did prior to the acquisition. The most recent radiation safety program audit performed on March 20, 2019 included routine well counter and dose calibrator QC, leak testing of all non-exempt sealed sources, an area survey, annual refresher training for personnel, and an audit of all records including personnel and area badge doses, exit surveys, package receipt testing, decay-in-storage and disposal records. Some minor contamination found during the area survey was cleaned to background levels.

Item No: 5

If current decommissioning funding plans (DFP) will be changed as a result of the transfer, the revised DFP should be submitted. If other financial assurance documents will be changed as a result of the transfer, confirm that all financial assurance instruments associated with the license will be held in the transferee's name before the E-2 license is transferred, and as required by 10 CFR 30.35(f), the licensee must, within 30 days, submit financial instruments reflecting such changes.

Response:

Not applicable. This license does not authorize the possession and use of unsealed byproduct material of half-life greater than 120 days exceeding 10^5 times the applicable quantities set forth in 10 CFR 30, Appendix B, and as such a DFP is not necessary.

Item No: 6

Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.

Response:

Not applicable. The facility will not be subject to decommissioning. All regulatory records will continue to remain onsite.

Item No: 7

Confirm that both transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of the transfer, and that the transferee has been made aware of any open inspection items and its responsibility for possible resulting enforcement actions.

Response:

Both the transferor and transferee agree to transferring control of the licensed material and activity, and to the conditions of the transfer. There are no open inspection items and possible enforcement actions to the current Radioactive Materials License No. 21-32816-01.

Item No: 8

Confirm that the transferee will abide by all constraints, conditions, requirements, representations, and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

Response:

Covance Laboratories Inc. agrees to abide by all constraints, conditions, requirements, representations, and commitments of the transferor as described in the existing Radioactive Materials License No. 21-32816-01.

Item No: 9

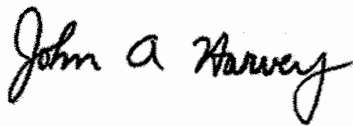
The transferee, in the case of fuel cycle facilities, shall provide documentation showing that it is financially qualified to conduct normal operations. The information can be in the form of income statements and balance sheet forecasts

Response:

Not applicable. Molecular Imaging, Inc. DBA MI Bioresearch is not a fuel cycle facility.

Please contact us if you have any questions or comments regarding this Transfer of Control. Dr. Harvey may be reached at (734) 678-7309 or john.harvey@westphysics.com; Mr. Smith may be reached at (317) 435-2641 or stephen.smith1@covance.com.

Kind regards,



John Harvey, Ph.D., CHP
Chief Medical & Health Physicist, West Physics
RSO, Molecular Imaging, Inc. DBA MI Bioresearch



Steve Smith
Director, Environmental Health and Safety, US and Europe
Covance Laboratories, Inc.

Song, Taehoon

From: Forster, Sara
Sent: Thursday, April 11, 2019 7:09 AM
To: Song, Taehoon; Pavon, Sandy; Sandrik, Lauren
Cc: Tomczak, Tammy
Subject: FW: Transfer of Control
Attachments: 2019-03-28 MI Bioresearch Request for RML Transfer of Control.pdf

Good morning,

This is a new request; I believe it is a Transfer of Control notification. Please scan in and forward to Tammy/Patty so it may be controlled in.

Thank you!

Sara Forster

From: Davidson, Brian [mailto:Brian.Davidson@covance.com]
Sent: Thursday, April 04, 2019 7:39 AM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] Transfer of Control

Hello Sara,
Attached is the Transfer of Control Document for the acquisition of MI Bioresearch by Covance Laboratories.

Regards,
Brian

Brian Davidson
Manager, Environmental Health & Safety
Radiation Safety Officer
O: 317.273.5369
M: 317.273.9710
Covance Central Laboratory Services, Inc.
8211 SciCor Drive, Indianapolis, IN 46214, USA



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