

## UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III 2443 WARRENVILLE RD. SUITE 210 LISLE, IL 60532-4352

JUN 2 4 2019

John Harvey, Ph.D., CHP Radiation Safety Officer Molecular Imaging, Inc. DBA MI Bioresearch 800 Technology Dr. Ann Arbor, MI 48108

Dear Dr. Harvey:

By letter date March 28, 2019, Molecular Imaging, Inc. doing business as (DBA) MI Bioresearch submitted to the U.S. Nuclear Regulatory Commission (NRC) a Request for Consent to indirect License Transfer of NRC Materials License No. 21-32816-01. Based on the information you provided, we understand that as a result of a sale of stock between Molecular Imaging, Inc. and Covance Laboratories Inc., control of Molecular Imaging Inc. will indirectly be transferred to Covance Laboratories Inc. We further understand that this transfer did not result in any change to the licensed name, licensed materials, persons using the license material, location of use of licensed material, or persons responsible for the licensee's radiation safety program.

Based on the above understandings and as more fully detailed in the enclosed NRC staff's Safety Evaluation Report which documents the NRC staff's review of the request, we have no objection to the indirect transfer.

Enclosed is Amendment No. 15 to your NRC Materials License No. 21-3281601. Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please note that Tittle 10 of the Code of Federal Regulations (10 CFR) 30.34(b) requires that no license issued or granted pursuant to the regulations in parts 30 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the NRC shall, after securing full information, find that the transfer is in accordance with the provisions of the Atomic Energy Act and shall give its consent in writing. Additional guidance regarding a transfer of control of a NRC materials license can be found in NUREG-1556, Volume 15, "Consolidated Guidance About Materials Licenses - Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," Revision 1 dated June 2016 which is posted on the NRC web page at <a href="https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v15/">https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v15/</a>.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy

and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <a href="http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html">http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html</a>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

rank P. D. Tran Health Physicist

Materials Licensing Branch

License No. 21-32816-01 Docket No. 030-38386

## Enclosures:

- 1) Amendment No. 15
- 2) Safety Evaluation Report