

SAFETY EVALUATION REPORT
PROPOSED TRANSFER OF CONTROL OF BYPRODUCT MATERIALS LICENSE
NUMBER 06-30624-01, Molecular NeuroImaging, LLC

DATE: November 6, 2017

DOCKET NO.: 030-35657

LICENSE NO.: 06-30624-01

LICENSEE: Molecular NeuroImaging, LLC
60 Temple Street, 8th Floor
New Haven, Connecticut 06510

TECHNICAL REVIEWER: Janice Nguyen, Senior Health Physicist, Region I

SUMMARY AND CONCLUSIONS

Molecular NeuroImaging, LLC is authorized by NRC License 06-30624-01 for the possession and use of byproduct material for the purposes of diagnostic and therapeutic studies, and for research and development as defined in 10 CFR 30.4. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to an indirect license transfer submitted by Molecular NeuroImaging, LLC, a wholly-owned subsidiary of Invicro, LLC. The indirect transfer will result from a sale between Konica Minolta IC, Inc. and Invicro, LLC. Under the planned transaction, Invicro, LLC will sell the majority ownership interest to Konica Minolta IC, Inc., and the remaining membership interests will continue to be held by Jack Hoppin, Christian Lackas, John Seibyl, M.D., and Kenneth Marek. Following the sale, Invicro, LLC will be an indirect subsidiary of Konica Minolta Precision Medicine, Inc. and Molecular NeuroImaging, LLC will remain a wholly owned subsidiary of Invicro, LLC. The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession number ML17272A795. The ADAMS package consists of the following documents: letter dated September 26, 2017 (redacted version) (ML17272A796), letter dated October 10, 2017 (ML17289A461), letter dated October 17, 2017 (ML17298B821), and letter dated October 23, 2017 (ML17298B823).

The licensee's request for consent to an indirect transfer of ownership was posted for public comment on the NRC website for 30 days in accordance with 10 CFR Part 2 and following the guidance provided in the NRC's Regulatory Issue Summary 2014-08. No comments were received from members of the public.

The request for consent was reviewed by NRC staff for an indirect transfer of control of a 10 CFR Part 30 license using the guidance in NUREG 1556, Volume 15, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," dated June 2016. The NRC staff finds that the information submitted by Molecular NeuroImaging, LLC and Konica Minolta IC, Inc. sufficiently describes and documents the transaction and commitments made by the both parties.

As required by 10 CFR 30.34 and section 184 of the Atomic Energy Act of 1954, as amended (the Act), NRC staff has reviewed the application and finds, as discussed below, that the proposed transfer of control is in accordance with the Act. The staff finds that, after the transfer of control, Molecular NeuroImaging, LLC will remain qualified to use byproduct material for the purpose requested, and will continue to have the equipment, facilities, and procedures needed to protect public health and safety, and promote the common defense and security.

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Web Based Licensing system, Molecular NeuroImaging, LLC has been an NRC licensee since April 5, 2001. The NRC conducted an inspection at the New Haven, Connecticut location on November 4, 2015, and no violations were identified. The commitments made by Molecular NeuroImaging, LLC and Konica Minolta IC, Inc. state that there will be:

- A. no change to the radiation safety officer listed on the NRC license;
- B. no change in personnel involved in licensed activities;
- C. no change in the locations, facilities, and equipment authorized in the NRC license;
- D. no change in the radiation safety program authorized in the NRC license; and
- E. no change in the organization's name listed in the NRC license.

Further, the licensee will maintain required surveillance records and decommissioning records as required by NRC regulations.

Konica Minolta, Inc. is a global digital technology company with significant activities in imaging and data analysis, optics, materials, and nano-fabrication. Headquartered in Tokyo, Japan, and with operations in more than 50 countries, Konica Minolta is a publically traded company that has more than 43,000 employees. Konica Minolta, Inc. wholly owns Konica Minolta Healthcare Americas, Inc., which currently holds multiple x-ray registrations issued by the New Jersey Department of Environmental Protection (under Facility ID No. 110424). They are also registered with the New Jersey Department of Health as a wholesaler for drug and medical devices (No. 5001766). Additionally, Konica Minolta Healthcare Americas, Inc. is registered with the Commonwealth of Massachusetts Department of Public Health (No. 65-0541) to provide installation and/or servicing of x-ray equipment. Konica Minolta Healthcare Americas, Inc. owns the majority interest in Konica Minolta Precision Medicine, Inc. (the proposed parent company to Invicro, LLC). For security purposes, Molecular NeuroImaging, LLC and Konica Minolta Precision Medicine, Inc., the parent post-closing, are considered to be known entities following the guidance provided by the NRC's Office of Nuclear Material Safety and Safeguards (NMSS): "Checklist to provide a basis for confidence that radioactive materials will be used as specified on the license," September 3, 2008 revision. The purpose of this checklist is for the NRC to obtain reasonable assurance from new license applicants or NRC licensees transferring control of licensed activities to ensure that the licensed material will be used for its intended purpose and not for malevolent use.

Molecular NeuroImaging, LLC is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 06-30624-01.

REGULATORY FRAMEWORK

Molecular NeuroImaging, LLC's License No. 06-30624-01 was issued under 10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material. The Commission is required by 10 CFR 30.34 to determine if the transfer of control is in accordance with the provisions of the Act and give its consent in writing.

10 CFR 30.34(b) states: "No license issued or granted pursuant to the regulations in this part and parts 31 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 Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing."

As previously indicated, the staff evaluation is based on guidance in NUREG-1556, Volume 15, Revision 1. Molecular NeuroImaging, LLC's request for consent describes an indirect transfer of control and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession number ML17272A795. The ADAMS package consists of the following agency documents: letter dated September 26, 2017 (redacted version) (ML17272A796, letter dated October 10, 2017 (ML17289A461), letter dated October 17, 2017 (ML17298B821), and letter dated October 23, 2017 (ML17298B823). After completion of the sale, Molecular NeuroImaging, LLC will continue as the licensee and remain in control of all licensed activities under Materials License No. 06-30624-01. The NRC staff finds that the request for consent adequately provides a complete and clear description of the transaction and is consistent with the guidance provided in Appendix E of NUREG-1556, Volume 15, Revision 1.

TRANSFeree'S COMMITMENT TO ABIDE BY THE TRANSFEROR'S COMMITMENTS

The NRC staff finds that the information submitted by Molecular NeuroImaging, LLC and Konica Minolta IC, Inc. sufficiently describes and documents the commitments made by both parties and is consistent with the guidance in NUREG-1556, Volume 15.

ENVIRONMENTAL REVIEW

An environmental assessment for this action is not required since this action is categorically excluded under 10 CFR 51.22(c)(21).

CONCLUSION

The staff has reviewed the request for consent submitted by the licensee with regard to an indirect transfer of control of byproduct materials license No. 06-30624-01 and consents to the transfer pursuant to 10 CFR 30.34(b).

Consistent with the guidance in NUREG-1556, Volume 15, Revision 1, the submitted information sufficiently describes the transaction; documents the understanding of the license and commitments of the transferee; demonstrates that personnel have the experience and training to properly implement and maintain the license and that they will maintain the existing records; and provides that, in the future, the transferee will abide by all existing commitments on the license.

Therefore, the staff concludes that the proposed transfer of control would not alter the previous findings, made under 10 CFR Part 30, that licensed operations will not be inimical to the common defense and security, or to the health and safety of the public.