

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

DATE: August 25, 2016

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

SUMMARY AND CONCLUSIONS

Molecular NeuroImaging, LLC (MNI) is authorized by U.S. Nuclear Regulatory Commission (NRC) License 06-30624-01 for the possession and use of byproduct material for purposes of medical diagnosis, therapy, and research and development. The U.S. NRC staff reviewed a request for consent to a direct license transfer submitted by MNI that resulted from the acquisition of MNI by inviCRO, LLC (CRO). Following the transaction that occurred on February 5, 2016, all MNI ownership units were transferred to CRO and MNI became a wholly owned subsidiary of CRO. The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession number ML16159A106 (which includes letter dated May 24, 2016 (ML16159A109), email dated August 19, 2016, with attachments, and letter dated August 24, 2016, with attachments).

The licensee's request for consent to a direct 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 a direct change in control of a 10 CFR Part 30 license using the guidance 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," dated November 2000. The NRC staff finds that the information submitted by MNI sufficiently describes and documents the transaction and commitments made by CRO and NMI.

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 that the proposed change in control is in accordance with the Act. The staff finds that, after the acquisition, MNI 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 promotes the security of licensed material.

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Licensing Tracking System (LTS), MNI has been an NRC licensee authorized to use byproduct material for medical and research purposes since April 5, 2001. The NRC conducted a main office inspection of MNI on November 4, 2015, and no violations were identified during this inspection. CRO has held Massachusetts license number 55-0692 authorized for medical and research purposes since October 24, 2013. The State of Massachusetts conducted a main office inspection of CRO on August 7, 2014, and no violations were identified during this inspection. The commitments made by MNI and CRO state that, absent NRC approval, MNI (License No. 06-30624-01):

- A. will not change the radiation safety officer listed in the NRC license;
- B. will not change the personnel involved in licensed activities;
- C. will not change the locations, facilities, and equipment authorized in the NRC license;
- D. will not change the radiation safety program authorized in the NRC license;
- E. will not change the organization's name listed in the NRC license; and
- F. will keep regulatory required surveillance records and decommissioning records.

For security purposes, MNI and CRO are considered known entities following the guidance provided by the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) '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 that the licensed material will be used for its intended purpose and not for malevolent use.

MNI 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

MNI License No. 06-30624-01 was issued under 10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material. The NRC is required by 10 CFR 30.34(b) to determine if the change of control is in accordance with the provisions of the Act and give its consent to the transaction in writing.

10 CFR 30.34(b)(1) 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. As discussed in NUREG-1556, Volume 15, the NRC is generally using the term “change of control” rather than the statutory term “transfer” to describe the variety of events that could require prior notification and written consent of the NRC. The central issue is whether the authority over the license has changed. MNI’s request for consent describes a direct change of control resulting from a planned acquisition of MNI by CRO. Following the completion of the acquisition, MNI will become a wholly owned subsidiary of CRO, and as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS package accession number ML16159A106 (which includes letter dated May 24, 2016 (ML16159A109), email dated August 19, 2016, with attachments, and letter dated August 24, 2016, with attachments). After completion of the acquisition, MNI will continue as the licensee and remain in control of all licensed activities under NRC 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 F of NUREG-1556, Volume 15.

TRANSFEREE’S COMMITMENT TO ABIDE BY THE TRANSFEROR’S COMMITMENTS

The NRC staff finds that the information submitted by MNI sufficiently describes and documents the commitments made by MNI and CRO, and is consistent with the guidance in NUREG-1556, Volume 15.

ENVIRONMENTAL REVIEW

An environmental assessment for this action is not required since this consent to the described transfer of control and the associated administrative license amendment are categorically excluded under 10 CFR 51.22(c)(21).

CONCLUSION

The staff has reviewed the request for consent submitted by both parties with regard to a direct change of control of byproduct materials license No. 06-30624-01 and consents to the transaction pursuant to 10 CFR 30.34(b).

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

Therefore, the NRC staff concludes that the proposed change in 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.