SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE NUMBERS 24-04206-01, 24-04206-02 AND 24-04206-05MD, MALLINCKRODT NUCLEAR MEDICINE LLC

DATE: November 28, 2016

DOCKET NOS.: 030-00001
030-38173
030-10801

LICENSE NOS.: 24-04206-01
24-04206-02
24-04206-05MD

LICENSEE: Mallinckrodt Nuclear Medicine LLC
2703 Wagner Place
Maryland Heights, MO 63043

TECHNICAL REVIEWER: Bryan A. Parker, Senior Health Physicist

SUMMARY AND CONCLUSIONS

Mallinckrodt Nuclear Medicine LLC is authorized by NRC License Nos. 24-04206-01, 24-04206-02 and 24-0420-05MD for the possession and use of byproduct material for manufacturing and distribution of medical product distribution, research and development, and production of accelerator-produced radionuclides. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to an indirect license transfer submitted by Mallinckrodt Nuclear Medicine LLC that will result from a sell of its interest from Mallinckrodt plc to GLO Bidco US LLC, which is owned and controlled by CapVest Partners LLP. The transaction is scheduled to be finalized on or after December 1, 2016. The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) accession number ML16250A581.

The request for consent was reviewed by NRC staff for an indirect change in control of 10 CFR Part 30 licenses using the guidance in NUREG 1556, Volume 15, Revision 1, "Consolidated Guidance About Materials Licenses - 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 Mallinckrodt Nuclear Medicine LLC, sufficiently describes and documents the transaction and commitments made by Mallinckrodt plc and CapVest Partners LLP.

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 change of control, Mallinckrodt Nuclear Medicine LLC remains qualified to use byproduct material for the purposes 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 Web-Based Licensing system (WBL), Mallinckrodt Nuclear Medicine LLC, has been an NRC licensee since October 8, 1958. The NRC conducted main office inspections of the three licenses for Mallinckrodt Nuclear Medicine LLC as follows: 1) License No. 24-04206-01 - last inspected on January 12-15, 2016 and four non-cited violations were identified during this inspection; 2) License No. 24-04206-02 - last inspected on May 12-16, 2014 and no violations were identified during this inspection; and 3) License No. 24-04206-05MD - last inspected on April 2-6, 2012 and no violations were identified during this inspection.

The licensee stated that Mallinckrodt Nuclear Medicine LLC - License Nos. 24-04206-01, 24-04206-02 and 24-0420-05MD:

A. will not change the Radiation Safety Officers listed in the NRC licenses;

B. will not change the personnel involved in licensed activities;

C. will not change the locations, facilities, and equipment authorized in the NRC licenses;

D. will not change the radiation safety program authorized in the NRC licenses;

E. will not change the organization's name listed in the NRC licenses; and

F. will keep regulatory required surveillance records and decommissioning records.

Mallinckrodt Nuclear Medicine LLC will be solely owned by, and be an indirect subsidiary of, CapVest Partners LLP, which is a leading European mid-market private equity firm headquartered in London. CapVest owns or is invested in several other industries worldwide including foods, healthcare, and waste collection. CapVest also owns IBA Molecular which has (or has had) several NRC licenses for nuclear pharmacy as well as many similar licenses in Agreement States. Many of these licenses are now under the name of Zevacor, but still owned by IBA Molecular. Therefore, for security purposes, CapVest Partners LLP is considered a known entity 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.

Mallinckrodt Nuclear Medicine LLC is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 24-04206-05MD, but is required to have decommissioning financial assurance for License Nos. 24-04206-01 and 24-04206-02.

REGULATORY FRAMEWORK

Mallinckrodt Nuclear Medicine LLC's License Nos. 24-04206-01, 24-04206-02 and 24-0420-05MD were 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 change 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 directly, 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. As discussed in this NUREG, 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. Mallinckrodt Nuclear Medicine LLC's request for consent describes an indirect change of control resulting from one top-tier party purchasing a part of another corporation and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS accession number ML16250A581. After the transaction is completed on or after December 1, 2016, Mallinckrodt Nuclear Medicine LLC will continue as the licensee and remains in control of all licensed activities under Materials License Nos. 24-04206-01, 24-04206-02 and 24-0420-05MD. 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 Mallinckrodt Nuclear Medicine LLC sufficiently describes and documents the commitments made by Mallinckrodt plc and CapVest Partners LLP and is consistent with the guidance in NUREG-1556, Volume 15, Revision 1.

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 with regard to an indirect change of control of Byproduct Materials License Nos. 24-04206-01, 24-04206-02 and 24-0420-05MD and approves the application 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, Revision 1.

Therefore, the 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.

NRC FORM 386 (RIII)
(4-2004)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
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