

**SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR MALLINCKRODT, LLC
BYPRODUCT MATERIALS LICENSE NOS. 24-04206-01, 24-04206-02, 24-04206-05MD,
24-17450-01 AND SOURCE MATERIALS LICENSE NO. STB-401**

DATE: June 17, 2013

DOCKET NOS.: 030-00001
030-38173
030-10801
030-12559
040-06563

LICENSE NOS.: 24-04206-01
24-04206-02
24-04206-05MD
24-17450-01
STB-401

LICENSEE: Covidien plc (parent of Mallinckrodt, LLC)
444 McDonnell Blvd.
Hazelwood, MO 63042

TECHNICAL REVIEWER: Bryan A. Parker
Health Physicist
DNMS/MLB
Region III

SUMMARY AND CONCLUSIONS

Mallinckrodt, LLC is authorized by several NRC Licenses for the possession and use of byproduct material at multiple locations for various purposes, including manufacture and distribution of radiopharmaceuticals and research and development. The U. S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to an indirect license transfer submitted by Covidien plc (the parent company of Mallinckrodt, LLC) that will result from an intercompany reorganization. Covidien plans to spin off all of its pharmaceutical operations to Mallinckrodt plc. Mallinckrodt, LLC will become one of the companies under the new parent company, Mallinckrodt plc. The indirect transfer of control was requested in letters dated March 25, 2013 and April 22, 2013 [Agency Documents Access and Management System (ADAMS) accession numbers ML13084A436 and ML13112A816, respectively].

The request for consent was reviewed by NRC staff for an indirect change in control of Title 10 of the Code of Federal Regulations (CFR) Part 30 licenses and a 10 CFR Part 40 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 Covidien sufficiently describes and documents the transaction and commitments made by Mallinckrodt plc and Covidien.

Enclosure

As required by 10 CFR 30.34(b) 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 plc will remain 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 Licensing Tracking System (LTS), Mallinckrodt, LLC has been an AEC/NRC licensee since October 8, 1958 (License No. 24-04206-01). The NRC conducted main office inspections of each of the Mallinckrodt, LLC licenses affected by this transaction. Below are the results of the most recent inspections:

- A. License No. 24-04206-01 – Routine inspection on April 2-6, 2012, one violation for a package survey not conducted properly in 2011 (IR 030-00001-12-01);
- B. License No. 24-04206-02 – Routine inspection on April 2-6, 2012, no violations identified (IR 030-38173-12-01);
- C. License No. 24-04206-05MD – Routine inspection on April 2-6, 2012, no violations identified (IR 030-10801-12-01);
- D. License No. 24-17450-01 – Routine inspection on October 27, 2011, no violations identified (IR 030-12559-11-01);
- E. License No. STB-401 – Routine inspection on March 15, 2013, no violations identified (IR 040-06563-13-01);

The commitments made by Mallinckrodt plc and Covidien state that Mallinckrodt, LLC:

- 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 programs 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.

This transaction will spin off the pharmaceutical operations which have been licensed by the NRC for many years, most recently through Covidien. Therefore, for security purposes, Mallinckrodt plc 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, LLC is required to have decommissioning financial assurance based on the types and amount of material authorized in License Nos. 24-04206-01, 24-04206-02, 24-17450-01 and STB-401. Mallinckrodt, LLC will maintain all current financial assurance mechanisms in place.

REGULATORY FRAMEWORK

Mallinckrodt, LLC's License Nos. 24-04206-01, 24-04206-02, 24-04206-05MD and 24-17450-01 were issued under 10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material and STB-401 was issued under 10 CFR Part 40, Domestic Licensing of Source Material. The Commission is required by 10 CFR 30.34(b) and 40.46(a) 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)(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."

10 CFR 40.46(a) states: "No license issued or granted pursuant to the regulations in this part 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, 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. Covidien's request for consent describes an indirect change of control resulting from a planned intercompany reorganization between Mallinckrodt, LLC's parent company Covidien and Mallinckrodt plc. Following the completion of the transaction, Mallinckrodt, LLC will indirectly, through Covidien, become part of Mallinckrodt plc and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS accession number ML13084A436. After completion of the merger, Mallinckrodt LLC will continue as the licensee and remain in control of all licensed activities under Materials License Nos. 24-04206-01, 24-04206-02, 24-04206-05MD, 24-17450-01 and STB-401. 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 Covidien sufficiently describes and documents the commitments made by Covidien and Mallinckrodt plc, and is consistent with the guidance in NUREG-1556, Volume 15.

ENVIRONMENTAL REVIEW

Environmental assessments for these actions are not required since these actions 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 an indirect change of control of Byproduct Materials License Nos. 24-04206-01, 24-04206-02, 24-04206-05MD, 24-17450-01 and STB-401 and consents to the indirect transfer of control pursuant to 10 CFR 30.34(b) and 40.46(a).

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 staff concludes that the proposed change in control would not alter the previous findings, made under 10 CFR Parts 30 and 40, that licensed operations will not be inimical to the common defense and security, or to the health and safety of the public.