

**SAFETY EVALUATION REPORT
PROPOSED TRANSFER OF CONTROL OF BYPRODUCT MATERIALS LICENSE
NUMBER 24-17450-01, MALLINCKRODT LLC**

DATE: May 14, 2020

DOCKET NO.: 030-12559

LICENSE NO.: 24-17450-01

LICENSEE: ST Shared Services LLC
(formerly Mallinckrodt LLC)
Research and Development
675 McDonnell Boulevard
Hazelwood, Missouri 63042

TECHNICAL REVIEWER: Bryan A. Parker, Senior Health Physicist, Region III

SUMMARY AND CONCLUSIONS

Mallinckrodt LLC is authorized by NRC License 24-17450-01 for the possession and use of byproduct material for the purposes of research and development as defined in 10 CFR 30.4. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request dated November 22, 2019, for consent to a direct license transfer submitted by Mallinckrodt LLC, a wholly-owned subsidiary of Mallinckrodt plc. The direct transfer occurred on March 3, 2020, and resulted from an intracompany transfer from Mallinckrodt LLC to ST Shared Services LLC. As a result, ST Shared Services LLC became a direct wholly-owned subsidiary of Mallinckrodt plc and a new sister company of Mallinckrodt LLC. The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) accession number ML19329D896. A followup document is also in ADAMS: letter dated March 4, 2020 (ML20065J638).

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 and was removed from posting on January 17, 2020.

The request for consent was reviewed by NRC staff for a direct transfer of control of a 10 CFR Part 30 license using the guidance in NUREG 1556, Volume 15, Rev. 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 Mallinckrodt LLC 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 that the proposed

transfer of control is in accordance with the Act. The staff finds that, after the transfer of control, ST Shared Services 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, Mallinckrodt LLC has been an NRC licensee since March 23, 1977. The NRC conducted an inspection at the licensee's location on December 15, 2017, and no violations were identified. The commitments made by ST Shared Services LLC state that there will be:

- A. no change to the radiation safety officer listed on the NRC licenses;
- 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.

This licensee was associated for decades with another Mallinckrodt license (License No. 24-04206; Docket No. 030-00001) until that company was recently sold and became Curium. Also, this is an intracompany transfer from an existing company under Mallinckrodt plc (Mallinckrodt LLC) and a newly-created company under the same (ST Shared Services LLC). Therefore, for security purposes, ST Shared Services LLC is considered to be a known entity 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 application," January 29, 2019 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.

ST Shared Services LLC is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 24-17450-01.

REGULATORY FRAMEWORK

Mallinckrodt LLC's License No. 24-17450-01 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, Rev. 1. Mallinckrodt LLC’s request for consent describes a direct transfer of control and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) accession number ML19329D896. A followup document is also in ADAMS: letter dated March 4, 2020 (ML20065J638). After completion of the transfer, ST Shared Services LLC continued as the licensee and remains in control of all licensed activities under Materials License No. 24-17450-01. 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, Rev. 1.

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

The NRC staff finds that the information submitted by Mallinckrodt LLC and ST Shared Services LLC sufficiently describes and documents the commitments made by both parties and is consistent with the guidance in NUREG-1556, Volume 15, Rev. 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 by the licensee with regard to a direct transfer of control of byproduct materials License No. 24-17450-01 and consents to the transfer pursuant to 10 CFR 30.34(b).

Consistent with the guidance in NUREG-1556, Volume 15, Rev. 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.