

Via Federal Express

September 21, 2015

Bryan Parker
Materials Licensing Section
United States Nuclear Regulatory Commission – Region III
2442 Warrenville Road, Suite 210
Lisle, IL 60352-4352

RE: Notification of Asset Transfer; Request for Concurrence of No Change of Control Under 10 CFR 30.34(b)

Dear Mr. Parker:

As we discussed on September 16, 2015, this letter is to notify the Nuclear Regulatory Commission (NRC) that on or about January 22, 2016, Mallinckrodt plc plans to complete an internal corporate reorganization that will result in the assets associated with the licenses described in Exhibit A to this notification being transferred to a new entity known as Mallinckrodt Nuclear Medicine LLC. This legal entity has the same ultimate parent company as the current licensee, Mallinckrodt LLC. Based upon a review of NUREG 1556, Volume 15, (2000) (“Consolidated Guidance about Materials Licenses, Guidance about Changes in Control and about Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses”), Mallinckrodt believes that this transfer of assets does not constitute a transfer of control, and seeks concurrence from the NRC regarding this evaluation.

Mallinckrodt plc, an Irish public limited company, indirectly owns all of the stock of Mallinckrodt LLC, a Delaware limited liability company. Mallinckrodt LLC owns legal title to the property, plant and equipment subject to the licenses or permits described in Exhibit A to this notification. As part of an internal transaction to streamline the ownership structure underneath Mallinckrodt plc and its assets, certain steps have occurred or will occur in the future. The following is a simplified summary of the steps: (1) a new legal entity, Mallinckrodt Nuclear Medicine LLC, a Delaware limited liability company, has been established; (2) the assets associated with the property, plant and equipment associated with the licenses referenced in Exhibit A will be transferred from Mallinckrodt LLC to Mallinckrodt Nuclear Medicine LLC; (3) Mallinckrodt LLC will submit license amendment requests to amend the name of the licensee from Mallinckrodt LLC to Mallinckrodt Nuclear Medicine LLC on the licenses referenced in Exhibit A. In addition, the license amendment request will address financial assurance.

As mentioned, none of these transactions involve any legal entities which are not affiliated with Mallinckrodt plc. All of the movement of assets and ownership is within the group of companies all wholly owned indirectly by Mallinckrodt plc. The assets associated with the licenses are being transferred from one indirect subsidiary of Mallinckrodt plc to another indirect subsidiary of Mallinckrodt plc.

By this letter, Mallinckrodt LLC is notifying the NRC that the above referenced transaction is planned to occur on or about January 22, 2016. On or about the date the transaction is

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completed, an additional correspondence will be sent to your office confirming the assets have been transferred from Mallinckrodt LLC to Mallinckrodt Nuclear Medicine LLC. Mallinckrodt is providing the following information to assist you in your review of the transaction.

1. The name of the new licensee will be Mallinckrodt Nuclear Medicine LLC. Its headquarters address will remain at the current location.

Mallinckrodt Nuclear Medicine LLC
675 McDonnell Blvd
Hazelwood, MO 63042

2. All contact information used for the existing licenses including telephone number(s) and names will remain the same.
3. There will be no changes in personnel having control over the license and the officers and managers of Mallinckrodt Nuclear Medicine LLC will be the same as Mallinckrodt LLC.
4. The following is a simplified summary of the steps: (1) a new legal entity, Mallinckrodt Nuclear Medicine LLC, a Delaware corporation has been established; (2) the assets associated with the property, plant and equipment associated with the licenses referenced in Exhibit A will be transferred from Mallinckrodt LLC to Mallinckrodt Nuclear Medicine LLC; (3) Mallinckrodt LLC will submit license amendment requests to amend the name of the licensee from Mallinckrodt LLC to Mallinckrodt Nuclear Medicine LLC on the licenses referenced in Exhibit A. In addition, the license amendment request will address financial assurance.
5. There are no planned changes to the organization, location, facility, equipment or procedures. If changes which may impact the licenses are planned in the future, the NRC will be notified as necessary.
6. All records retained in connection with the licenses will be maintained at the current location.
7. Mallinckrodt Nuclear Medicine LLC agrees to abide by all commitments and representations within the licenses and will maintain all license terms, conditions, and requirements.

A review of the above-referenced NUREG 1556, Volume 15, strongly supports the conclusion that this transaction does not constitute a change of control. Specifically, example 2 in Appendix D, at page D-5 under "No Change of Control," closely mirrors this transaction. There, the assets of four materials licensees were restructured, resulting in a change in corporate form. All four licensees were affiliated with the same parent, both before and after the transaction. There were no changes in personnel having control over licensed activities, the licensed materials at issue, the facility, the equipment or procedures. The restructured entity assumed full liability for facility decontamination, agreed to abide by the licenses, and accepted full responsibility for the site. Under these circumstances, NRC concluded that there was no change of control pursuant to 10 CFR 30.34(b). Since all of these conditions also apply to Mallinckrodt's planned transaction, we believe the outcome should also be the same – *i.e.*, no change of control.



Mallinckrodt requests that NRC review the information in this letter and indicate whether or not NRC agrees with Mallinckrodt's position that this transaction does not constitute a change of control. Please note that we would appreciate your expeditious review of this request for concurrence. If you have any questions or need additional information regarding the foregoing, please contact me at 314-654-6878.

Very Truly Yours,

A handwritten signature in black ink that reads "Eric Berry". The signature is written in a cursive, flowing style.

Eric Berry
Vice President – Environmental Law

Enc:

Exhibit A – Permit List

cc: file
Manuel Diaz (Mallinckrodt)
Dale Eymann (Mallinckrodt)
Alan Faust (Mallinckrodt)
Jim Schuh (Mallinckrodt)

Exhibit A
List of Impacted Mallinckrodt LLC Licenses

24-04206-01
24-04206-02
24-04206-05MD

TO REUSE: Cover or mark through any previous shipping inform.

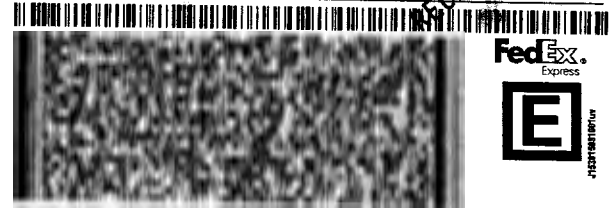
ORIGINATOR
BARBARA JOHNSON
TYCO MALLINCKRODT
675 MCDONNELL BLVD
HAZELWOOD, MO 63042
UNITED STATES US

SHIP DATE: 21 SEP 13
ACTWGT: 0.50 LB
CAD: 3742267/NET3670
BILL SENDER

TO **BRYAN A. PARKER**
US NUCLEAR REGULATORY COMMISSION
MATERIALS LICENSING BRANCH, REG.III
2443 WARRENSVILLE RD., SUITE 210
LISLE IL 60532

(630) 829-9500 REF: 008011420680-6656
INV. PO. DEPT.

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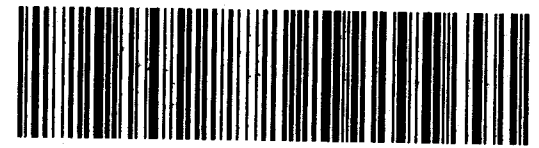


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