



Via Federal Express

February 22, 2016

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
NRC Letter to Mallinckrodt dated October 27, 2015
Mallinckrodt letter to NRC dated September 21, 2015
NRC Licenses 24-04206-01, 24-04206-02 and 24-04206-05MD**

Dear Mr. Parker:

This letter is to notify the Nuclear Regulatory Commission (NRC) that Mallinckrodt plc has completed an internal corporate reorganization as described in our letter to the NRC dated September 21, 2015. As a result of that reorganization all assets associated with the licenses listed in Exhibit A have been transferred to a new legal entity known as Mallinckrodt Nuclear Medicine LLC. This transaction was effective January 22, 2015. As a result of the transaction Mallinckrodt is submitting this license amendment request to amend the name of the licensee from Mallinckrodt LLC to Mallinckrodt Nuclear Medicine LLC.

If you have any questions regarding this amendment request please do not hesitate to contact me at (314)654-7981.

Sincerely,

A handwritten signature in black ink that reads "James R. Schuh".

James R. Schuh
Director, EHS – Nuclear Operations

Enc:

Exhibit A – Permit List

cc: Eric Berry (Mallinckrodt)
Manuel Diaz (Mallinckrodt)
Debbie Piskura (USNRC – RIII)
Sumit Verma (Mallinckrodt)

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Exhibit A
List of Impacted Mallinckrodt LLC Licenses

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

APPLICATION FOR MATERIALS
LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollections.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,
SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

☐

A. NEW LICENSE

☒

B. AMENDMENT TO LICENSE NUMBER

24-04206-02

☐

C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

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

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

2703 Wagner Place
Maryland Heights, MO 63043

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

James R. Schuh

BUSINESS TELEPHONE NUMBER

(314) 654-7981

BUSINESS CELLULAR TELEPHONE NUMBER

(314) 393-4558

BUSINESS EMAIL ADDRESS

James.Schuh@Mallinckrodt.com

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

- a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*)
(See 10 CFR 170 and Section 170.31)

FEE CATEGORY

AMOUNT
ENCLOSED \$

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Sumit Verma / Site Director

SIGNATURE

DATE

22 FEB 16

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

SHIPPING ORDER
(NON-HAZARDOUS GOODS)

SHIP TO Bryan Parker materials Licensing Section U.S. NRC Region III 2442 Warrenville Rd. Ste 210 Liste IL, 60532-4352		ORIGINATOR Jim Schuh DEPARTMENT EHS Director TELEPHONE EXT 6547806 DATE ISSUED 2/22/16 3-15-16		ORDER NO. 027238 SHIPPED FROM MALLINCKRODT, INC. 2703 WAGNER PL. MARYLAND HTS., MO 63043	
ROUTING FEK		ACCOUNT NO. (20 DIGIT) 011-010-08-0033			
DELIVERY INSTRUCTIONS <input checked="" type="checkbox"/> NEXT DAY DELIVERY <input type="checkbox"/> SECOND DAY DELIVERY <input type="checkbox"/> OTHER (SPECIFY) TRAFFIC APPROVAL [Signature] DATE 15 MAR 16 PIC/PURCHASING APPROVAL DATE SHIPPED DATE					

IMPORTANT NOTICE:

IF YOU THINK THE MATERIALS BEING SHIPPED QUALIFIES, OR MAY POSSIBLY QUALIFY, AS ANY ONE OF THE HAZARD CLASSES LISTED BELOW, REFER TO HAZARDOUS MATERIAL SHIPPING ORDER J-625.
 EXPLOSIVES, FLAMMABLE GAS, FLAMMABLE LIQUID, FLAMMABLE SOLID, OXIDIZING SUBSTANCES, POISONOUS AND INFECTIOUS SUBSTANCES, RADIOACTIVE, CORROSIVES, MISC. DANGEROUS GOODS.

STORE ROOM MATERIAL							
CODE	INDEX	LOCATOR	LOT NO.	DESCRIPTION	QTY. REQ'D	QTY. FILLED	EXTENSION

TOOLS/EQUIPMENT/MECH SUPPLIES REPAIR		
QUANTITY	DESCRIPTION	ASSET OR ITEM NO.

MISCELLANEOUS MATERIAL	
QUANTITY	DESCRIPTION (BE SPECIFIC)
1	Letter

FedEx

Express

earthsmart

FedEx carbon-neutral
envelope shipping

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RT493
10:30
1997
03:16
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Align top of FedEx Express shipping label here.

ORIGIN ID: ZSVA (800) 525-3689 SHIPPING DEPT MALLINCKRODT NUCLEAR MEDICINE LLC. 2703 WAGNER PLACE MARYLAND HEIGHTS, MO 63043 UNITED STATES US	SHIP DATE: 15MAR16 ACTWGT: 0.1 LB CAD: 00520807/CAFE2915 BILL SENDER
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TO US NRC REGION III / BRYAN PARKER
MATERIALS LICENSING SECTION
2443 WARRENVILLE RD
STE 210
LISLE IL 605324537
REF: 027238

DEPT: SHIPPING

 **FedEx Express** 

TRK# 9042 4662 1697 WED - 16 MAR 10:30A
0201 PRIORITY OVERNIGHT

XH ENLA 60532
IL-US ORD



Part # 156148-434 NRT V3 10-08 **

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