

September 13, 2012

Materials Licensing Section
 U.S. Nuclear Regulatory Commission
 2443 Warrenville Road, Ste. 210
 Lisle, IL 60532-4352
 Attention: Mr. Kevin Null

RE: License Number 24-04206-05MD; Docket Number 030-10801

Dear Mr. Null:

This submission is a license amendment request for the subject license. A copy of a completed Form 313 is attached hereto. Specifically, Mallinckrodt is requesting that Section 8 of the license be revised to allow a maximum of 20.0 curies per generator vs. the existing 19.0 curie limit. This change applies to the Ultra-TechneKow[®] Dry Ship Top Elution (DTE) Molybdenum-99/Technetium-99m Generator, NDA No. 17-243.

The reason for this change is to improve customer satisfaction in regard to activity yields for the generators. There are no plans to increase the labeled activity of the generator. The following table provides the updated information. This includes the maximum activity per container and the maximum container surface dose rate at the time of shipment for generators with Lead, Tungsten and Depleted Uranium shields.

Catalog Number	Labeled Size at Calibration (mCi)	Max. Activity Per Container at Time of Shipment (mCi)	Max. Dose Rate at Container Surface at Time of Shipment (mR/hr)
N881/N895 DTE Generator with Lead Safe	1000 to 7500	7900	1530
N881/N895 DTE Generator with Tungsten Safe	5000 to 7500	7900	1110
N881/N895 DTE Generator with Depleted Uranium Safe	6000 to 19000	20000	330

If there is anything that we can do to facilitate the processing of this amendment request or if you have any questions about this submission please contact me, Dan Hoffman at 314-654-7906 or Tim Dowell at 314-654-7975.

Sincerely,



Dexter Evans
Site Director

cc (w/o enclosure):

Tim Dowell – Mallinckrodt
Dan Hoffman -- Mallinckrodt
Jim Schuh – Mallinckrodt
Kay Yoder – Mallinckrodt

APPLICATION FOR MATERIALS LICENSE

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS
 DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
 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 24-04206-05MD

C. RENEWAL OF LICENSE NUMBER _____

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

Mallinckrodt LLC
 2703 Wagner Place
 Maryland Heights, MO 63043

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Mallinckrodt LLC
 2703 Wagner Place
 Maryland Heights, MO 63043

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Daniel Hoffman

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
(314) 654-7906	(314) 625-1881
BUSINESS EMAIL ADDRESS	
daniel.hoffman@covidien.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 *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY	AMOUNT ENCLOSED
3D	\$ 0.00

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, 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

Dexter Evans, Site Director

SIGNATURE

Dexter Evans

DATE

13 sep 12

FOR NRC USE ONLY

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

FedEx

Express

ORIGIN ID: ZSVA (800) 525-3689
SHIPPING DEPT
MALLINCKRODT MEDICAL INC.
2703 WAGNER PLACE
MARYLAND HEIGHTS, MO 63043
UNITED STATES US

SHIP DATE: 13SEP12
ACTWT: 0.3 LB
CAD: 0052080/CAFE2604

BILL SENDER

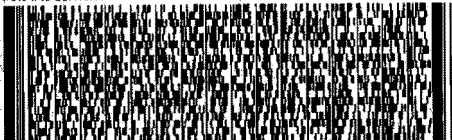
TO ATTN: MR.K. NULL
US NRC REGION III
2443 WARRENVILLE RD. STE 210

LISLE IL 605324352

RECEIVED SEP 14 2012

REF: 024765

DEPT: SHIPPING



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Express



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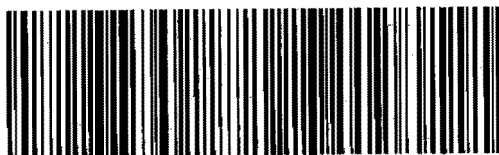
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PRIORITY OVERNIGHT

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IL-US ORD

Part # 155 48-404 NRIT V3 10-09



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