



**Mallinckrodt LLC**

September 15, 2011

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

RE: License Number 24-04206-02; Docket Number 030-38173

Dear Mr. Null:

This letter and attachments constitute a request for amendment to the above referenced license. The purpose of this amendment request is to add additional short-lived isotopes of copper and zinc which are incidentally produced in our cyclotrons during the processing of targets used in the process of manufacturing Ga-67, In-111 and Tl-201.

Specifically, we are requesting that Sections 6 through 8 of the license be amended to include the information provided in the following table.

<b>Byproduct Material</b>	<b>Chemical or Physical Form</b>	<b>Maximum Amount</b>
Cu-61	Any	200 curies
Cu-62	Any	16,200 curies
Zn-62	Any	600 curies
Zn-63	Any	8,700 curies

The proposed use for these isotopes is "production and storage incident to production activities".

It should be noted that this amendment request is not based on any change of operations. It simply serves to improve the accuracy of the maximum activities of the specified isotopes. As a result of the chemical separation processes employed and the short half-lives of the isotopes they are not detected in our final products.

A completed NRC Form 313 is also attached hereto in support of this amendment request.

If you have any questions regarding this submission please contact me, Dan Hoffman at 314-654-7906 or Tim Dowell at 314-654-7975.

Sincerely,

  
Dexter Evans  
Site Director

cc: Tim Dowell – Mallinckrodt  
Dan Hoffman – Mallinckrodt  
Jim Schuh – Mallinckrodt  
Kay Yoder – Mallinckrodt

**NRC FORM 313** U.S. NUCLEAR REGULATORY COMMISSION  
 (05-2012)  
 10 CFR 30, 32, 33,  
 34, 35, 36, 39, and 40

APPROVED BY OMB: NO. 3150-0120

EXPIRES: (05/31/2015)

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 Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to [InfoCollects.Resource@nrc.gov](mailto:InfoCollects.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.

**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 24-04206-02

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 (314) 654-7906	BUSINESS CELLULAR TELEPHONE NUMBER (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
3S	\$ 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 (000) 625-3689  
SHIPPING DEPT.  
MALLINCKRODT MEDICAL INC.  
2703 WAGNER PLACE  
MARYLAND HEIGHTS, MO 63043  
UNITED STATES US

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

BILL SENDER

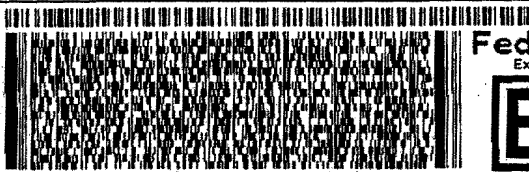
TO ATTN: MR.K. NULL  
US NRC REGION III  
2443 WARRENVILLE RD. STE 210

LISLE IL 605324352

REF: 024765

DEPT: SHIPPING

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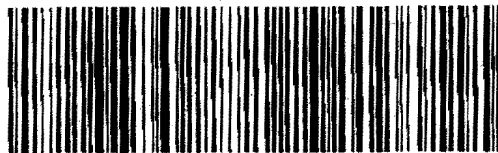
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