

<p><b>NRC FORM 313</b> (05-2012) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40</p> <p style="text-align: center;"><b>U.S. NUCLEAR REGULATORY COMMISSION</b></p> <p style="text-align: center;"><b>APPLICATION FOR MATERIALS LICENSE</b></p>	<p><b>APPROVED BY OMB: NO. 3150-0120</b></p> <p>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 <a href="mailto:infocollects.Resource@nrc.gov">infocollects.Resource@nrc.gov</a>, 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.</p>	<p><b>EXPIRES: (06/31/2015)</b></p>
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**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.**

<p><b>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</b></p> <p>OFFICE OF FEDERAL &amp; STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001</p> <p><b>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:</b></p> <p><b>IF YOU ARE LOCATED IN:</b></p> <p>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,</p> <p><b>SEND APPLICATIONS TO:</b></p> <p>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</p>	<p><b>IF YOU ARE LOCATED IN:</b></p> <p>ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, <b>SEND APPLICATIONS TO:</b></p> <p>MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352</p> <p>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,</p> <p><b>SEND APPLICATIONS TO:</b></p> <p>NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1600 E. LAMAR BOULEVARD ARLINGTON, TX 76011-4511</p>
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**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.**

<p><b>1. THIS IS AN APPLICATION FOR (Check appropriate item)</b></p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input checked="" type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER <u>24-17450-01</u></p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>	<p><b>2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)</b></p> <p>Mallinckrodt LLC 675 McDonnell Blvd, Hazelwood, MO 63042</p>
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<p><b>3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</b></p> <p>Mallinckrodt LLC 675 McDonnell Blvd, Hazelwood, MO 63042</p>	<p><b>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</b></p> <p>John Snider</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%;">BUSINESS TELEPHONE NUMBER (314) 654-8563</td> <td style="width:50%;">BUSINESS CELLULAR TELEPHONE NUMBER (314) 713-5276</td> </tr> <tr> <td colspan="2">BUSINESS EMAIL ADDRESS <a href="mailto:john.snider@covidien.com">john.snider@covidien.com</a></td> </tr> </table>	BUSINESS TELEPHONE NUMBER (314) 654-8563	BUSINESS CELLULAR TELEPHONE NUMBER (314) 713-5276	BUSINESS EMAIL ADDRESS <a href="mailto:john.snider@covidien.com">john.snider@covidien.com</a>	
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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.

<p><b>5. RADIOACTIVE MATERIAL</b></p> <p>a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time</p>	<p><b>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</b></p>		
<p><b>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.</b></p>	<p><b>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</b></p>		
<p><b>9. FACILITIES AND EQUIPMENT.</b></p>	<p><b>10. RADIATION SAFETY PROGRAM.</b></p>		
<p><b>11. WASTE MANAGEMENT</b></p>	<p><b>12. LICENSE FEES (See 10 CFR 170 and Section 170.31)</b></p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:70%;">FEE CATEGORY</td> <td style="width:30%;">AMOUNT ENCLOSED \$</td> </tr> </table>	FEE CATEGORY	AMOUNT ENCLOSED \$
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, 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

<p>CERTIFYING OFFICER - TYPE OR PRINTED NAME AND TITLE</p> <p>Richard A. Roberts, Ph.D., Sr Director</p>	<p>SIGNATURE</p> <p><i>Richard A Roberts</i></p>	<p>DATE</p> <p>11 Sep 2012</p>
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FOR NRC USE ONLY					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

# **Mallinckrodt**

September 7, 2012

United States Nuclear Regulatory Commission  
Region III  
Nuclear Materials Licensing Branch  
2443 Warrenville Road, STE 210  
Lisle, IL 60532-4352

RE: License No: 24-17450-01, Amendment Request 30,

Mallinckrodt, LLC requests an amendment to license 24-17450-01 to make changes to the new uses evaluation form, attached, in order to develop new lines of products.

In developing these new lines of products there are anticipated rare occurrences where the researcher may have to make direct hand contact with the source, this is currently not allowed under the evaluation. Work procedures, also attached, will be utilized in these rare cases to ensure that the extremity dose is properly evaluated and that all doses are kept as low as reasonably achievable.

## RADIOACTIVE MATERIAL USE PROTOCOL

The Radiation Safety Committee approves all uses of Radioactive Material. Please enter the appropriate information in the text field under each section:

- I. Protocol Number (Obtain from RSO):
- II. Protocol Title (*Please include the radioisotope in the title*):
- III. Authorized User Responsible for Protocol:
- IV. Radionuclide Data:
  - A. Isotope:
  - B. Half-life and mode of decay (*Please indicate significant decay products of parent and daughter isotopes*):
  - C. Chemical and physical form of radioisotope:
  - D. Maximum quantity of radioisotope to be on hand for use under this protocol (*Note: All Authorized Users should remain aware of the site license possession limits for radionuclides they work with; contact the RSO for specific limits if not known*):
  - E. Quantity of radioisotope to be used in each experiment under this protocol:
- V. Protocol Work Scope (*Describe in detail the experiment to be performed and the methodology to be used. Be specific and note any potential "unusual" occurrences. Include the chemicals and instruments that are to be used. If available, reference any previous work that is similar in nature to the work described here*):

**VI. Facilities to be used under this protocol (*Please describe the area (lab, floor, hood, etc.) where the work under this protocol will be performed. If radioactive material will be transported between work areas, please describe the transport procedure for the material*):**

**VII. Radiation Safety Issues:**

- A. If known, describe the expected biological fate of the unbound radionuclide or labeled compound being studied. Include the starting material, intermediates, and the final product. Indicate the human target organs if known.**
- B. Describe the general laboratory safety and radiation safety precautions and equipment to be used under this protocol. (*i.e., how time, distance and shielding will be used to maintain an ALARA approach to conducting the work under this protocol. Include decontamination procedures in the event of work area or personal contamination. For work involving volatile and/or radioiodinated materials, discuss extra precautions to be taken such as the use of ventilated work and storage areas, thyroid measurements, etc.*):**

- C. Forecast the approximate hand and whole body exposure using a worst case scenario of an unshielded source of radioactivity handled under the protocol. Use 1 cm distance for the hand dose calculations and 0.5 meter distance for the whole body dose calculations. If the radionuclide has more than one mode of decay (gamma and beta emitters), calculate the radiation exposures from each type of radiation. Indicate the reduction in exposure using the appropriate type of shielding:

**IF DIRECT HANDLING OF THE RADIOACTIVE MATERIAL IS REQUIRED FILL OUT AND ATTACH ATTACHMENT II! ATTACHMENT III must be completed after the experiment.**

Dose rate estimation of unshielded source at 1 cm:  
 Dose rate estimation of unshielded source at 50 cm:  
 Estimated time per procedure in which the source will be unshielded:

Shield thickness and material:  
 Dose rate estimation of shielded source at 1 cm:  
 Dose rate estimation of shielded source at 50 cm:  
 Estimated time per procedure in which the source will be shielded:

Forecasted extremity dose per procedure:  
 Forecasted whole body dose per procedure:  
 Anticipated number of time procedure will be performed a year:  
 Total annual forecasted dose:

- D. Describe disposal arrangements for the waste generated under this protocol (*If the isotope's half-life is greater than 30 days or if radioiodine is used, special arrangements should be made with the Health Physics staff*).

VIII. List all the personnel who are expected to perform the work described under this protocol. Before submitting the hard copy of this protocol to the Radiation Safety Committee for final review and authorization, have the individuals below read this protocol and sign their names in the appropriate space:

User's Name	User/Worker	Signature	Date

*Note: Authorized users have sufficient experience and education enabling them to safely carry out or supervise the experiment.*

**IX. RSO and RSC Recommendations:**

**RSC Authorization:**

\_\_\_\_\_  
**Chairperson**                      **Date**

\_\_\_\_\_  
**RSO**                                      **Date**

\_\_\_\_\_  
**Committee Member**              **Date**

\_\_\_\_\_  
**Committee Member**              **Date**

\_\_\_\_\_  
**Committee Member**              **Date**

\_\_\_\_\_  
**Committee Member**              **Date**

*NOTE: The minimum staff considered acceptable for a quorum for approval of new uses is: chairperson, RSO, management representative, committee person representing the department/area from whom the protocol originated and any other committee member whose field of expertise is necessary to assure all safety aspects have been addressed.*

Attachment II Direct Contact Assessment Form

- I. Protocol Number :**
- II. Protocol Title (*Please include the radioisotope in the title*):**
- III. After exploring opportunities that would not have the researcher make contact with the source, list and describe why each is not reasonable. Include the use of tongs and shielding.**
- IV. A dry run must be set up and observed by the RSO and at least one member of the RSC. The dry run should include performing the procedure listed in the protocol at least three times. After the dry run;**

**List the date of the dry run:**

**List the participants that observed the dry run:**

**Were any reasonable methods identified during the dry run that would prevent contact with the source;**

**How long was the direct contact:**

V. Using Varskin, or other validated software in kind, estimate the contact dose:

VI. Anticipated number of times this procedure will be performed per year:

VII. RSO and RSC Recommendations:

RSC Authorization:

\_\_\_\_\_  
Chairperson                      Date

\_\_\_\_\_  
Committee Member              Date

\_\_\_\_\_  
Committee Member              Date

\_\_\_\_\_  
RSO                                  Date

\_\_\_\_\_  
Committee Member              Date

\_\_\_\_\_  
Committee Member              Date



Attachment III Direct Contact Dose Tracking Form

**Name:**

**Date:**

1. What is your current extremity doses:
  
2. Which protocol did you perform:
  
3. How many times did you perform the procedure listed in the protocol today?
  
4. List the estimated hand dose per protocol listed in Attachment II of the protocol:
  
5. List the current ALARA Goal:
  
6. What is your total hand extremity dose year to date after today? Does this goal exceed the ALARA goal listed in step 5?

At the end of each day, where direct contact occurred, fill out this form and submit to the Health Physics Department.

**Note to HP Staff: Update the dose estimate for the individual.**

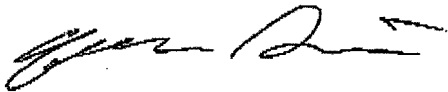
Reviewed by;  
Signature:

Date:

Please feel free to contact Richard Roberts at (314)654-3363 or myself at (314)654-8563 if you have any questions or need further information.

Thank you,

Sincerely,

A handwritten signature in black ink, appearing to read "John Snider". The signature is fluid and cursive, with a prominent initial "J" and a long, sweeping underline.

**John Snider**  
Radiation Safety Officer/EH&S Specialist

675 McDonnell Blvd.  
Farmingdale, NY 11735

**Mallinckrodt**

facsimile transmittal

To: NRC material Licensing, BURL Fax: (630)-515-1078

From: John Sullivan Date: 9-11-2012

Re: Amendment 30 Pages: 11

CC: \_\_\_\_\_

- Urgent
- For Review
- Please Comment
- Please Reply
- Please Recycle

