

APPLICATION FOR MATERIALS LICENSE - MEDICAL

INSTRUCTIONS - Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.

1.a. NAME AND MAILING ADDRESS OF APPLICANT (institution, firm, clinic, physician, etc.) INCLUDE ZIP CODE

Mallinckrodt, Inc.
Diagnostic Imaging Services
675 McDonnell Blvd.
St. Louis, MO 63134

TELEPHONE NO.: AREA CODE (314) 895-2227

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (If different from 1.a.) INCLUDE ZIP CODE

Mallinckrodt, Inc.
Diagnostic Imaging Services
20 Independence Ct.
Folcroft, PA 19032

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Richard J. Costic

TELEPHONE NO.: AREA CODE (314) 895-2227

3. THIS IS AN APPLICATION FOR: (Check appropriate item)

a. ☐ NEW LICENSE

b. ☒ AMENDMENT TO LICENSE NO. 37-21345-01MD

c. ☐ RENEWAL OF LICENSE NO. _____

4. INDIVIDUAL USERS (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)

See Attached Amendment.

5. RADIATION SAFETY OFFICER (RSO) (Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)

N/A

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES			IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP III			GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		
10 CFR 35.100, SCHEDULE A, GROUP VI					

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. (Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
N/A for this amendment.			
8508300117 850722 REG1 LIC30 37-21345-01MD PDR			

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8, Rev. _____ Date: _____

Item 7, and 9 through 23 not applicable for this amendment.

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One)	
<input type="checkbox"/>	Names and Specialties Attached; and	<input type="checkbox"/>	Appendix G Rules Followed; or
<input type="checkbox"/>	Duties as in Appendix B; or _____ (Check One)	<input type="checkbox"/>	Equivalent Rules Attached
<input type="checkbox"/>	Equivalent Duties Attached	16. EMERGENCY PROCEDURES (Check One)	
8. TRAINING AND EXPERIENCE		<input type="checkbox"/>	Appendix H Procedures Followed; or
<input checked="" type="checkbox"/>	Supplements A & B Attached for Each Individual User; and	<input type="checkbox"/>	Equivalent Procedures Attached
<input type="checkbox"/>	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES (Check One)	
9. INSTRUMENTATION (Check One)		<input type="checkbox"/>	Appendix I Procedures Followed; or
<input type="checkbox"/>	Appendix C Form Attached; or	<input type="checkbox"/>	Equivalent Procedures Attached
<input type="checkbox"/>	List by Name and Model Number	18. WASTE DISPOSAL (Check One)	
10. CALIBRATION OF INSTRUMENTS		<input type="checkbox"/>	Appendix J Form Attached; or
<input type="checkbox"/>	Appendix D Procedures Followed for Survey Instruments; or _____ (Check One)	<input type="checkbox"/>	Equivalent Information Attached
<input type="checkbox"/>	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)	
<input type="checkbox"/>	Appendix D Procedures Followed for Dose Calibrator; or _____ (Check One)	<input type="checkbox"/>	Appendix K Procedures Followed; or
<input type="checkbox"/>	Equivalent Procedures Attached	<input type="checkbox"/>	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
<input type="checkbox"/>	Description and Diagram Attached	<input type="checkbox"/>	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM		<input type="checkbox"/>	Appendix L Procedures Followed; or _____ (Check One)
<input type="checkbox"/>	Description of Training Attached	<input type="checkbox"/>	Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133)	
<input type="checkbox"/>	Detailed Information Attached	<input type="checkbox"/>	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (Check One)		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
<input type="checkbox"/>	Appendix F Procedures Followed; or	<input type="checkbox"/>	Detailed Information Attached
<input type="checkbox"/>	Equivalent Procedures Attached	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
<input type="checkbox"/>		<input type="checkbox"/>	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE <small>(Check appropriate box)</small>		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	FILM		
	TLD		
	OTHER (Specify)		
b. FINGER	FILM		
	TLD		
	OTHER (Specify)		
c. WRIST	FILM		
	TLD		
	OTHER (Specify)		

d. OTHER (Specify)

N/A for this amendment.

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY

STATE

ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

b. APPLICANT OR CERTIFYING OFFICIAL (Signature)

(1) NAME (Type of Print)

Richard J. Costic

(2) TITLE

Director, Diagnostic Imaging Svcs

(1) LICENSE FEE CATEGORY

Byproduct Material

(2) LICENSE FEE ENCLOSED: \$ 230.00

c. DATE

June 6, 1985

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.
5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

BETWEEN: William O. Miller, Chief.
License Fee Management Branch
Office of Administration -

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: Mallincrodt, Inc.

Application Dated: 5/31/85

Control No.: 03939

License No.: 37-21345 - OIMD

2. FEE ATTACHED

Amount: \$ 230.00

Check No.: 041868

3. COMMENTS

Signed Brandia Platchek

Date 6/11/85

02500

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 3C - \$230

2. Correct Fee Paid. Application may be processed for:

Amendment /

Renewal /

License /

Signed B Jackson

Date 6/20/85