NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved by OMB 3150-0041

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
1827 Belt Way Drive
St. Louis, MO 63114
TELEPHONE NO.: AREA CODE (314) 427-1555

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
1827 Belt Way Drive
St. Louis, MO 63114

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Todd A. Warren, R.Ph. B.C.N.P.
TELEPHONE NO.: AREA CODE (314) 427-1555

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

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 24-04206-08MD
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.)*

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRA-CAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		

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
8707090398 870223 REG3 LIC30 24-04206-08MD PDR N/A for this amendment			

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: _____

Items 7-23 N/A on this amendment

7. MEDICAL ISOTOPES COMMITTEE

- [ ] Names and Specialties Attached; and
- [ ] Duties as in Appendix B; or *(Check One)*
- [ ] Equivalent Duties Attached

8. TRAINING AND EXPERIENCE

- [ ] Supplements A & B Attached for Each Individual User; and
- [ ] Supplement A Attached for RSO.

9. INSTRUMENTATION *(Check One)*

- [ ] Appendix C Form Attached; or
- [ ] List by Name and Model Number

10. CALIBRATION OF INSTRUMENTS

- [ ] Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
- [ ] Equivalent Procedures Attached; and
- [ ] Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
- [ ] Equivalent Procedures Attached

11. FACILITIES AND EQUIPMENT

- [ ] Description and Diagram Attached

12. PERSONNEL TRAINING PROGRAM

- [ ] Description of Training Attached

13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

- [ ] Detailed Information Attached

14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*

- [ ] Appendix F Procedures Followed; or
- [ ] Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*

- [ ] Appendix G Rules Followed; or
- [ ] Equivalent Rules Attached

16. EMERGENCY PROCEDURES *(Check One)*

- [ ] Appendix H Procedures Followed; or
- [ ] Equivalent Procedures Attached

17. AREA SURVEY PROCEDURES *(Check One)*

- [ ] Appendix I Procedures Followed; or
- [ ] Equivalent Procedures Attached

18. WASTE DISPOSAL *(Check One)*

- [ ] Appendix J Form Attached; or
- [ ] Equivalent Information Attached

19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*

- [ ] Appendix K Procedures Followed; or
- [ ] Equivalent Procedures Attached

20. THERAPEUTIC USE OF SEALED SOURCES

- [ ] Detailed Information Attached; and
- [ ] Appendix L Procedures Followed; or *(Check One)*
- [ ] Equivalent Procedures Attached

21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)

- [ ] Detailed Information Attached

22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS

- [ ] Detailed Information Attached

23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b

- [ ] Detailed Information Attached

CONTROL NO. 82295

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			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 to 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)*

(1) LICENSE FEE CATEGORY: Byproduct material

(2) LICENSE FEE ENCLOSED: $ 120 (amendment)

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*: Todd A. Warren

(1) NAME *(Type or Print)*: Todd A. Warren, R.Ph. B.C.N.P.

(2) TITLE: Radiation Safety Officer

c. DATE: September 26, 1986

NRC FORM 313M (9-81)

CONTROL NO. 82295

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.

MERCER

Southern School of Pharmacy
Department of Pharmaceutical Sciences

Date: August 8, 1986

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Janna Millenbine

Field of Training	Location and Date(s) of Training	Type and Length of Training	
		Lecture/ Laboratory Courses (Hours)	Supervised Laboratory Experience (Hours)
A. Radiation Physics and Instrumentation	Mercer University School of Pharmacy 345 Boulevard, N.E. Atlanta, GA 30312 July 7 - Aug. 8, 1986	68	17
B. Radiation Protection	"	31	14
C. Mathematics Pertaining to the use and Measurement of Radioactivity	"	16	4
D. Radiation Biology	"	20	
E. Radiopharmaceutical Chemistry	"	30	
	TOTALS:	165 hrs.	35 hrs.

MERCER UNIVERSITY
345 Boulevard, NE
Atlanta, Georgia 30312
(404) 688-6291

Michael P. Kavula, Jr., Pharm.D.
Associate Professor of
Pharmaceutical Sciences

DOCUMENTING RADIOISOTOPE HANDLING EXPERIENCE

Name: Janna D. Millenbine

EXPERIENCE WITH RADIOACTIVE MATERIAL. (Actual Use of Radioisotopes Under the Supervision of an Authorized User)

ISOTOPE	MAXIMUM AMOUNT USED AT ONE TIME	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE (actual clock hours) (Need 500 total)*	TYPES OF USE 1, 2, 3, 4, 5, 6 (see key below)
Tc-99m Ga-67 Tl-201 I-131 I-125 I-123 Mo-99 Xe-133 In-111 Co-57 Co-137 Co-60 Se-75 P-32 Cr-51 Fe-59	20 Ci 1 Ci 1 Ci 500 mCi 40 mCi 500 mCi 30 Ci 2 Ci 50 mCi 20 mCi 1 mCi 1 mCi 10 mCi 35 mCi 10 mCi 1 mCi	Mallinckrodt, Inc. Diagnostic Imaging Services St.Louis, MO	Feb. 17 - March 21 1986 (200 hrs) June 30 - July 3 1986 (32 hrs) Aug. 11 - 29, 1986 (120 hrs) Sept. 2 - 26, 1986 (152 hrs) Total hours: 500	1 through 6

Key for "Type of Use"

The number or numbers entered under "Type of Use" correspond to experience in the following activities:

1. Ordering, receiving, and unpacking radioactive materials safely, including performance of related radiation surveys.
2. Calibration of dose calibrators, scintillation detectors, and survey meters.
3. Calculation dispensing, and calibration of patient doses, including proper use of radiation shields.
4. Appropriate internal control procedures to prevent mislabeling errors.
5. Emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests.
6. Elution of Technetium-99m generator systems, assay and testing of the eluate for Molybdenum-99 contamination, and processing the eluate with reagent kits to prepare Technetium-99m labeled radiopharmaceuticals.

*This number reflects the minimum hours needed to qualify for licenses.

MERCER

Southern School of Pharmacy
Department of Pharmaceutical Sciences

Date: August 8, 1986

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Gregg Stolinski

Field of Training	Location and Date(s) of Training	Type and Length of Training	
		Lecture/ Laboratory Courses (Hours)	Supervised Laboratory Experience (Hours)
A. Radiation Physics and Instrumentation	Mercer University School of Pharmacy 345 Boulevard, N.E. Atlanta, GA 30312 July 7 - Aug. 8, 1986	68	17
B. Radiation Protection	"	31	14
C. Mathematics Pertaining to the use and Measurement of Radioactivity	"	16	4
D. Radiation Biology	"	20	
E. Radiopharmaceutical Chemistry	"	30	

TOTALS: 165 hrs. 35 hrs.

MERCER UNIVERSITY
345 Boulevard, NE
Atlanta, Georgia 30312
(404) 688-6291

CONTROL NO. 82295

Michael P. Kavula, Jr., Pharm.D.
Associate Professor of
Pharmaceutical Sciences

DOCUMENTING RADIOISOTOPE HANDLING EXPERIENCE

Name: Gregg G. Stolinski

EXPERIENCE WITH RADIOACTIVE MATERIAL. (Actual Use of Radioisotopes Under the Supervision of an Authorized User)

ISOTOPE	MAXIMUM AMOUNT USED AT ONE TIME	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE (actual clock hours) (Need 500 total)*	TYPES OF USE 1, 2, 3, 4, 5, 6 (see key below)
Tc-99m	20 Ci	Mallinckrodt, Inc.	Jan. 6 - Feb. 7	1 through 6
Ga-67	1 Ci	Diagnostic Imaging	1986	
Tl-201	1 Ci	Services	(200 hrs)	
I-131	500 mCi	St.Louis, MO.		
I-125	40 mCi		June 2 - July 3	
I-123	500 mCi		1986	
Mo-99	30 Ci		(152 hrs)	
Xe-133	2 Ci			
In-111	50 mCi		Aug. 11 - Sept. 5	
Co-57	20 mCi		1986	
Co-137	1 mCi		(148 hrs)	
Co-60	1 mCi			
Se-75	10 mCi			
P-32	35 mCi			
Cr-51	10 mCi			
Fe-59	1 mCi			
			Total hours: 500	

Key for "Type of Use"

The number or numbers entered under "Type of Use" correspond to experience in the following activities:

1. Ordering, receiving, and unpacking radioactive materials safely, including performance of related radiation surveys.
2. Calibration of dose calibrators, scintillation detectors, and survey meters.
3. Calculation dispensing, and calibration of patient doses, including proper use of radiation shields.
4. Appropriate internal control procedures to prevent mislabeling errors.
5. Emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests.
6. Elution of Technetium-99m generator systems, assay and testing of the eluate for Molybdenum-99 contamination, and processing the eluate with reagent kits to prepare Technetium-99m labeled radiopharmaceuticals.

*This number reflects the minimum hours needed to qualify for licenses.

CONTROL NO. 82295