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
675 McDonnell Blvd.
St. Louis, MO 63134

TELEPHONE NO.: AREA CODE( ) _____ _____

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
9455 Midwest Avenue
Garfield Heights, OH 44125

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. 24-04206-07MD
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)*
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
N/A for this amendment.			

CONTROL NO. 7 9 1 9 5

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)*
[ ] Names and Specialties Attached; and	[ ] Appendix G Rules Followed; or
[ ] Duties as in Appendix B; or *(Check One)*	[ ] Equivalent Rules Attached
[ ] Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*
8. TRAINING AND EXPERIENCE	[ ] Appendix H Procedures Followed; or
[X] Supplements A & B Attached for Each Individual User; and	[ ] Equivalent Procedures Attached
[ ] Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES *(Check One)*
9. INSTRUMENTATION *(Check One)*	[ ] Appendix I Procedures Followed; or
[ ] Appendix C Form Attached; or	[ ] Equivalent Procedures Attached
[ ] List by Name and Model Number	18. WASTE DISPOSAL *(Check One)*
10. CALIBRATION OF INSTRUMENTS	[ ] Appendix J Form Attached; or
[ ] Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	[ ] Equivalent Information Attached
[ ] Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*
[ ] Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	[ ] Appendix K Procedures Followed; or
[ ] Equivalent Procedures Attached	[ ] Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	20. THERAPEUTIC USE OF SEALED SOURCES
[ ] Description and Diagram Attached	[ ] Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	[ ] Appendix L Procedures Followed; or *(Check One)*
[ ] Description of Training Attached	[ ] Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)
[ ] Detailed Information Attached	[ ] 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
	[ ] Detailed Information Attached
[ ] Appendix F Procedures Followed; or	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b
[ ] Equivalent Procedures Attached	[ ] Detailed Information Attached

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 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)

(1) LICENSE FEE CATEGORY
Byproduct Material

(2) LICENSE FEE ENCLOSED $ 230.00

RECEIVED
JUN 20 1985
REGION III

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*
Richard J. Costic

(2) TITLE
Director, Diagnostic Imaging Svcs

c. DATE
June 6, 1985

NRC FORM 313M (9-81)

CONTROL NO. 7 9195

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.

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Page 1. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES*

Name: NATALIE SCHOCH

Location of Training	Date(s) of Attendance	Course Title	Total Clock Hours of Course	Breakdown of Course Content in Clock Hours*				
				Radiation Physics & Instrumentation (need total of 85) **	Radiation Protection (need total of 45) **	Math Pertaining to Radioactivity (need total Of 20) **	Radiation Biology (need total of 20) **	Radiopharmaceutical Chemistry (need total of 30) **
Duquesne Univ	8/83 to 12/83	Bionucleonics	45	28	5	3	7	2
Duquesne Univ	8/83 to 12/83	Bionucleonics Lab	45	35	-	10	-	-
Duquesne Univ	1/84 to 5/84	Advanced Bionucleonics & Radiopharmacy	45	12	6	5	5	17
Duquesne Univ	1/84 to 5/84	Advanced Bionucleonics & Radiopharmacy Lab	45	25	8	4	8	-
Duquesne Univ	8/84 to 12/84	Health Physics	45	-	30	-	-	15
			TOTAL HOURS 100		49	22	20	34

* Note: Show a breakdown of hours by institutions, dates, and subjects. List each hour only once (i.e., under the most applicable subject category).

** This number reflects Minimum hours needed to qualify for licensure.

Name: NATALIE SCHOCH

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 I-123 Ga-67 Tl-201	20Ci 1Ci 1Ci 1Ci	Duquesne University Radioisotope Laboratory	90	2, 6
Xe-133 Se-75 Co-57	2Ci 250mCi 10mCi	Mallinckrodt DIS Pittsburgh, PA	160	1, 2, 3, 4, 5, 6
Cs-137 Ba-133 Co-60 In-111 I-131 Cr-51 I-125 Fe-59 P-32	20mCi 277uCi 1mCi 10mCi 1Ci 10mCi 5mCi 5mCi 35mCi	Mallinckrodt DIS Garfield Hts, OH	250	1, 2, 3, 4, 5, 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.