

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

McCullough-Hyde Memorial Hospital
110 North Poplar Street
Oxford, Ohio 45056

TELEPHONE NO.: AREA CODE (513) 523 - 2111

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

same

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Joseph Brandabur, M.D.

TELEPHONE NO.: AREA CODE (513) 523 - 2111

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

a. ☐ NEW LICENSE

b. ☐ AMENDMENT TO LICENSE NO.

c. ☒ RENEWAL OF LICENSE NO. 34-18728-01

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

Mary C. Moebius, M.D.
Joseph Brandabur, M.D.

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.)

Joseph Brandabur, M.D.

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	X	2	IODINE-121 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	as needed
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP III	X	3000	GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	200
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. (Isotopes 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
<p>Applicant: Mary C. Moebius, M.D.</p> <p>Check No. 31411</p> <p>Amount Fee Category \$5.80</p> <p>Type of Fee 7C Rm</p> <p>Date Check Rec'd 5/1/85</p> <p>Received By [Signature]</p>			

APR 29 1985

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: _____

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

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	FILM	Siemens Health Physics Services	monthly
	TLD		
	OTHER (Specify)		
b. FINGER	FILM		
	TLD	Siemens Health Physics Services	monthly
	OTHER (Specify)		
c. WRIST	FILM		
	TLD		
	OTHER (Specify)		

d. OTHER (Specify)

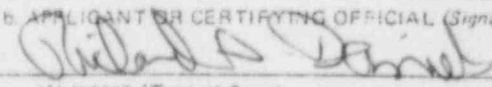
25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL		
NAME OF HOSPITAL		b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.
MAILING ADDRESS		c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.
CITY	STATE ZIP CODE	

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) LICENSE FEE CATEGORY 10 CFR 170.31 7.C. Renewal		(1) NAME (Type or Print) Richard A. Daniels
(2) LICENSE FEE ENCLOSED \$ 580.00		(2) TITLE Hospital Administrator
		c. DATE April 5, 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.

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Radiation Safety Committee consists of the following members:

Joseph Brandabur, M.D., Chairman, Pathologist

Mary C. Moebius, M.D., Radiologist

James Kereiakes, Ph.D., Radiologic Physicist

Donald Barnhart, Ph.D., Microbiologist

James Goldey, M.D., Emergency Room Physician

Richard Daniels, Hospital Administrator

Ms. Donna Eyster, R.N., M.S., Nursing Staff

Mrs. Lynn Brown, A.R.R.T., Radiology Supervisor

Mrs. Carole Ritzi, A.R.R.T., C.N.M.T., Nuclear Medicine Technologist

APPENDIX B

MEDICAL ISOTOPES COMMITTEE*

Responsibility

The committee is responsible for:

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.
2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license.

Duties

The committee shall:

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.
2. Review the training and experience of all individuals who use radioactive material (including physicians, technologists, physicists, and pharmacists) and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.
3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security, and house-

keeping personnel) are properly instructed as required by §19.12 of 10 CFR Part 19.

4. Review and approve all requests for use of radioactive material within the institution.
5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures.
6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspection, written safety procedures, and the adequacy of the institution's management control system.
7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
8. Maintain written records of all committee meetings, actions, recommendations, and decisions.
9. Ensure that the byproduct material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel, as specified in the license.

Meeting Frequency

The medical isotopes committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

* A rule is expected in 1981 that would change the name, composition, and functions of this committee.

Item No. 7
April 5, 1985

TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

Mary C. Moebius, M.D.

2. STATE OR TERRITORY IN WHICH EMPLOYED TO PRACTICE MEDICINE

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
General Radiology	Nuclear Medicine 3/1/82 - 4/30/82 5/1/83 - 6/30/83	

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TIME AND LENGTH OF TRAINING	
		LECTURE LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	UNIVERSITY OF CINCINNATI HOSPITAL	25	
b. RADIATION PROTECTION		9	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY		5	
d. RADIATION BIOLOGY		5	
e. RADIOPHARMACEUTICAL CHEMISTRY		9	

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Tc-99m	1.5 curie per elution (approx.)	University of Cincinnati	720 hours Clinical Nuclear Medicine - University of Cincinnati Hosp.	generator elution; kit preparations - more than 20 including: Tc-MAA Tc-sulfur colloid Tc-MDP Tc-DTPA Tc-glucoheptonate

Additional clinical and didactic material - 160 hours:

Clinical Nuclear Medicine Lectures - 50 hours

Clinical Nuclear Medicine Conferences - 60 hours

Radioisotope Physics - 30 hours

Research Conferences - 20 hours