

NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION <b>APPLICATION FOR MATERIALS LICENSE – MEDICAL</b>	Approved by OMB 3150-0041 Expires 9-30-83
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**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  Mercy Hospital 485 West Market Street Tiffin, Ohio 44883  TELEPHONE NO. AREA CODE 419 447 3130	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (If different from 1.a.) INCLUDE ZIP CODE  Same as 1.a.
2. PERSON TO CONTACT REGARDING THIS APPLICATION  Steve Spinosi, Consultant Nuclear Medicine Associates TELEPHONE NO. AREA CODE 216 641 5799	3. THIS IS AN APPLICATION FOR: (Check appropriate item) a. <input type="checkbox"/> NEW LICENSE b. <input checked="" type="checkbox"/> AMENDMENT TO LICENSE NO. 34-04492-02 c. <input type="checkbox"/> 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.)  Amend to Add:  Khalid R. Siddiqui, 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.)  No Change Check 13508 7/20 Amend 25 Amend 25

**6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE**

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS Date Type	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
The purpose of this amendment application is to:			
1. Add Khalid R. Siddiqui, M.D. as authorized user for Group VI and P-32 soluble & colloidal. See Akron General Hospital NRC license #34-03362-02 for training and experience.			
2. Revise survey procedures per Item #17.			

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REGION III

CONTROL NO. 79571

# 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 (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	
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		X 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	
Appendix F Procedures Followed; or		Detailed Information Attached	
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 <small>(Check appropriate box)</small>		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	FILM	No Change	
	TLD		
	OTHER (Specify)		
b. FINGER	FILM		
	TLD	No Change	
	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.

<p>a. LICENSE FEE REQUIRED <small>(See Section 170.31, 10 CFR 170)</small></p>	<p>b. APPLICANT OR CERTIFYING OFFICIAL (Signature)</p> <p style="font-family: cursive;">* Sister Mary Edwardine RSM</p> <p>(1) NAME (Type of Print)</p> <p>X Sister Mary Edwardine, R.S.M.</p>
<p>(1) LICENSE FEE CATEGORY</p> <p style="text-align: center;">7C</p>	<p>(2) TITLE</p> <p>X Administrator</p>
<p>(2) LICENSE FEE ENCLOSED \$ 120.00</p>	<p>c. DATE</p> <p>X August 12, 1985</p>

## 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.

## SURVEY PROCEDURE

- A. Routine elution, preparation and designated injection areas will be surveyed daily with a G-M survey meter and decontaminated, if necessary.
- B. Laboratory areas where only small quantities of radioactive material are used (less than 200 uCi) will be surveyed monthly.
- C. All other laboratory areas will be surveyed weekly.
- D. The weekly and monthly survey will consist of:
  - 1. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.
  - 2. A series of wipe tests to measure contamination levels. Analysis of wipe tests will be performed using a low level G-M survey meter.

The procedure will be as follows:

- a. Perform wipe tests.
- b. Place smear(s) in a "baggy" or disposable glove.
- c. Adjust response time to the longest time constant, if applicable.
- d. Select most sensitive range.
- e. Turn beta shield on probe to open position.
- f. Wait until reading stabilizes.
- g. Read and record background.
- h. Place smear in contact with open position of probe.
- i. Wait until the reading stabilizes.
- j. Read and record wipe results.

Action levels for smear analysis using the G-M survey meter will be set at any response above background. If action levels of removable contamination are found, decontamination efforts will be initiated to provide for clean-up or to prevent spread. In order to avoid unnecessary personnel exposure, contamination strongly suspected as being caused by Tc-99m may be shielded and/or covered to prevent spread and be allowed to decay.

Item #17  
1 of 2 pages  
Prepared: 8-7-85  
Lic. # 34-04492-02



E. A permanent record will be kept of the weekly or monthly survey results, including negative results. The record will include:

1. Location, date and type of equipment used.
2. Name of person conducting the survey.
3. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
4. Measured exposure rates, keyed to location on drawing (point out rates that require corrective action).
5. Detected contamination levels, keyed to locations on drawing.
6. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

Item #17  
2 of 2 pages  
Prepared: 8-7-85  
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