

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

<b>1.a. NAME AND MAILING ADDRESS OF APPLICANT</b> ( <i>institution, firm, clinic, physician, etc.</i> ) INCLUDE ZIP CODE Milton Medical Center 92 Highland St. Milton, MA 02186  TELEPHONE NO.: AREA CODE(     ) _____	<b>1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED</b> ( <i>If different from 1.a.</i> ) INCLUDE ZIP CODE  Same
<b>2. PERSON TO CONTACT REGARDING THIS APPLICATION</b> Kevin Henry Chief Nuclear Medicine Technologist TELEPHONE NO.: AREA CODE (617) <u>696</u> <u>4600</u>	<b>3. THIS IS AN APPLICATION FOR:</b> ( <i>Check appropriate item</i> ) a. <input type="checkbox"/> NEW LICENSE b. <input checked="" type="checkbox"/> AMENDMENT TO LICENSE NO. <u>20-15614-01</u> c. <input type="checkbox"/> RENEWAL OF LICENSE NO. _____
<b>4. INDIVIDUAL USERS</b> ( <i>Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.</i> ) William Cobb, M.D. (Certified in Internal Medicine)	<b>5. RADIATION SAFETY OFFICER (RSO)</b> ( <i>Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.</i> ) Robert Richter, M.D. RSO Neil Gaeta CHP (15-20 hours per year)

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	X	25
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	X	100
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. ( <i>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.</i> )			
ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
<div style="text-align: center;"> <b>8506110489 850313</b>  <b>REC1 LIC30</b>  <b>20-15614-01</b> </div> <div style="text-align: right; margin-top: 10px;"> <b>PDR</b> </div>			

# **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. 1 Date: October 1980

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 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 checked="" 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	<input type="checkbox"/>	FILM	
	<input type="checkbox"/>	TLD	
	<input type="checkbox"/>	OTHER <i>(Specify)</i>	
b. FINGER	<input type="checkbox"/>	FILM	
	<input type="checkbox"/>	TLD	
	<input type="checkbox"/>	OTHER <i>(Specify)</i>	
c. WRIST	<input type="checkbox"/>	FILM	
	<input type="checkbox"/>	TLD	
	<input type="checkbox"/>	OTHER <i>(Specify)</i>	

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			
CITY	STATE    ZIP CODE		
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 <i>(See Section 170.31, 10 CFR 170)</i>	b. APPLICANT OR CERTIFYING OFFICIAL <i>(Signature)</i> 
(1) LICENSE FEE CATEGORY: 7B	(1) NAME <i>(Type of Print)</i> Kenneth Richmond
(2) LICENSE FEE ENCLOSED: \$ <u>      \$140      </u>	(2) TITLE Hospital Administrator
	c. DATE November 28, 1984

## 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.



TRAINING AND EXPERIENCE  
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER  William E. Cobb, M.D.	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
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## 3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Internal Medicine		June 1976
Subspecialty certification in Endocrinology and Metabolism		June 1979

## 4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	(1) As a Fellow in Endocrinology and Metabolism at New England Medical Center, Boston, Ma. from July 1976 to June 1978 I spent hundreds of hours in the Endocrine Laboratory under direct supervision, learning to perform RIA's, to label peptide hormones and other laboratory procedures involving the use of radioisotopes, gamma counters and scintillation counters. During this training there were numerous laboratory conferences and informal instruction sessions on the handling of radioisotopes. In addition there was substantial interaction with the radiation physics department. Also, under the direct supervision of Dr. Seymour Reichlin and other Endocrine faculty I learned to determine therapeutic doses of $^{131}\text{I}$ in the treatment of thyrotoxicosis and thyroid carcinoma. I learned also how to calculate volume of $^{131}\text{I}$ solutions based on its specific activity and directly administered these therapies to patients. (please see reverse side)		
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
$^{131}\text{I}$	100 mCI	New England Medical Center Hospital	8 years	Therapy of hyperthyroidism and thyroid cancer.
$^{131}\text{I}$	100 mCI	Quincy City Hospital	6 years	Same
$^{125}\text{I}$	10 mCI	NEMCH	8 years	RIA, IMA, peptide labeling, etc.

4. Training Received in Basic Radioisotope Handling Techniques (cont'd)

2. As a Clinical Associate Physician and Assistant Professor of Medicine at the Tufts New England Medical Hospital I was a student in a "Basic Radioisotopes Course" which provided over 20 hours of classroom instruction in the theory and mathematics of radioisotopes. We used the text "A Basic Radioisotopes Course" by E. Webster, Ph. D., of the Massachusetts General Hospital. This course was given between September 1982 and June 1983 and was taught by Mr. Andrew McCauley, who is the supervisor of the CORE laboratory of the Clinical Research Unit at NEMCH, and Associate Professor of Chemistry at Northeastern University.

## PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

## 1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

## FULL NAME

William E. Cobb, M.D.

## STREET ADDRESS

100 Highland Street

## CITY

Milton

## STATE

MA

## ZIP CODE

02186

## KEY TO COLUMN C

## PERSONAL PARTICIPATION SHOULD CONSIST OF:

- 1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.
- 2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.
- 3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

## 2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION ✓	✓	Applicant has had continuous experience under supervision in the use of radioactive $^{131}\text{I}$ AND $^{125}\text{I}$ in diagnosis of thyroid functions, in-vitro labelling of peptide hormones, treatment of Graves' Disease and of thyroid carcinoma
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES ✓	✓	
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
OTHER			

**PRECEPTOR STATEMENT (Continued)**

**2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)**

ISOTOPE  A	CONDITIONS DIAGNOSED OR TREATED  B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION  C	COMMENTS  (Additional information or comments may be submitted in duplicate on separate sheets.)  D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		SEE REVERSE SIDE
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA ✓	✓	
	TREATMENT OF HYPERTHYROIDISM ✓		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

**3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING**

**4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:**

a. NAME OF SUPERVISOR

**Seymour Reichlin, M.D., Ph D.**

b. NAME OF INSTITUTION

**Tufts - New England Medical Center**

c. MAILING ADDRESS

**171 Harrison Avenue**

d. CITY

**Boston, Ma. 02111**

5. MATERIALS LICENSE NUMBER(S)

**6. PRECEPTOR'S SIGNATURE**

*Seymour Reichlin, M.D., Ph.D.*

**7. PRECEPTOR'S NAME (Please type or print)**

**Seymour Reichlin**

**8. DATE**

**August 15, 1984**



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: Milton Medical Center

Application Dated: 11/28/84

Control No.: 03281

License No.: 20-15614-01

2. FEE ATTACHED

Amount: \$ 140.00

Check No.: 001938

3. COMMENTS

Signed Bronco Platchek

Date 1/2/85

3/31/89  
7C B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 7C \$120

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

Amendment /

Renewal                     

License                     

Refunded \$20

Signed Frances Brown

Date 1/7/85