REQUEST FOR OMB REVIEW

(Under the Paperwork Reduction Act and Executive Order 12291)

Important — Read instructions (SF-83A) before completing this form. *Submit the required number of copies of SF-83, together with the material for which review is requested to:*

Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, D.C. 20503

1. Department/Agency and Bureau/Office originating request
U.S. Nuclear Regulatory Commission

3. Name(s) and telephone number(s) of person(s) who can best answer questions regarding request
Bob O'Connell (301) 427-4211

2. 6-digit Agency/Bureau number *(first part of 11-digit Treasury Account No.)*
3 1 0 2 0 0

4. 3-digit functional code *(last part of 11-digit Treasury Account No.)*
2 7 6

5. Title of Information Collection or Rulemaking
Application for Materials Licens
Medical - NRC form 313M

C. *Is this a rulemaking submission under Section 3504(h) of P.L. 96-511? (Check one)*
1 XX No (Section 3507 submission)
2 ☐ Yes, NPRM. Expected date of publication: _____
3 ☐ Yes, final rule. Expected date of publication. _____
Effective date: _____

6. A. *Is any information collection (reporting or recordkeeping) involved? (Check one)*
1 XX Yes and proposal is attached for review
2 ☐ Yes but proposal is not attached — skip to question D.
3 ☐ No — skip to question D.

B. *Are the respondents primarily educational agencies or institutions or is the purpose related to Federal education programs?*
☐ Yes XX No

D. At what phase of rulemaking is this submission made? *(Check one)*
1 XX Not applicable
2 ☐ Major rule, at NPRM stage
3 ☐ Major Final rule for which no NPRM was published
4 ☐ Major Final rule, after publication of NPRM
5 ☐ Nonmajor rule, at NPRM stage
6 ☐ Nonmajor rule, at Final stage

COMPLETE SHADED PORTION IF INFORMATION COLLECTION PROPOSAL IS ATTACHED

7. Current (or former) OMB Number
3150-0041

Expiration Date
9/30/81

8. Requested Expiration Date
9/30/84

12. Agency report form number(s)
NRC Form 313M

13. Are respondents only Federal agencies?
☐ Yes XX No

9. Is proposed information collection listed in the information collection budget?
X Yes ☐ No

10. Will this proposed information collection cause the agency to exceed its information collection budget allowance? *(If yes, attach amendment request from agency head.)*
☐ Yes XX No

14. Type of request *(Check one)*
1 ☐ preliminary plan
2 ☐ new *(not previously approved or expired more than 6 months ago)*
3 ☐ revision
4 ☐ extension *(adjustment to burden only)*
5 X extension *(no change)*
6 ☐ reinstatement *(expired within 6 months)*

11. Number of report forms submitted for approval -1
(NRC Form 313M)

15.

a. Approximate size of universe *(if sample)*	N/A
b. Size of sample	N/A
c. Estimated number of respondents or recordkeepers per year	500
d. Reports annually by each respondent *(item 25)*	1
e. Total annual responses *(item 15c x 15d)*	500
f. Estimated average number of hours per response	2
g. Estimated total hours of annual burden in Fiscal Year *(item 15e x 15f)*	1,000

16. Classification of Change in Burden *(explain in supporting statement)*

	No. of Responses	No. of Reporting Hours	Cost to the Public
a. In inventory	500	1,000	$
b. As proposed	500	1,000	$
c. Difference (b-a)	-0-	-0-	$

Explanation of difference (indicate as many as apply)

Adjustments

d. Correction-error	±	±	± $
e. Correction-reestimate	±	±	± $
f. Change in use	±	±	± $

Program changes

g. Increase	+	+	+ $
h. Decrease	—	—	— $

SUPPORTING STATEMENT
FOR
FORM NRC-313M
10 CFR PART 35, SECTION 35.4

A.1. Justification

(i) NRC regulations in 10 CFR Part 35, Section 35.4, require that applications for specific licenses to possess and use byproduct material in humans are to be filed on "Application for Materials License - Medical," Form NRC-313M.

(ii) The NRC staff will review the information submitted on Form NRC-313M to determine whether an applicant for a license has training, experience, equipment, facilities, and procedures for the use of byproduct material that are adequate to protect the public health and safety.

(iii) There is no source for the required information other than applicants.

(iv) NRC is the only Federal agency that requires the submission of information on radiation safety programs for the medical use of reactor-produced isotopes (byproduct material). NRC has closely coordinated its medical licensing program with FDA and other government agencies to assure that information requested is not duplicative.

(v) This application is only submitted for the initial license and for renewals every five years thereafter. The application process requires that licensees perform a comprehensive review of their entire radiation safety program to assure that all activities will be or are being conducted safely and in accordance with NRC regulations. The review and submission of the information required on the application form is essential to NRC's determination of whether the applicant has training, experience, equipment, facilities, and procedures for the use of byproduct material that are adequate to protect the public health and safety. Two hours is a reasonable period for the preparation and submission of this application form.

(vi) N/A

2. Description of Information Collection

(i) It is estimated that approximately 500 applications will be submitted to NRC annually on Form NRC-313M.

(ii) Applicants will fill in the information requested on Form NRC-313M and submit the original and one copy to NRC.

(iii) None.

(iv) N/A

(v) None.

(vi) The nature of the activities involved (e.g., medical use of byproduct materials by hospitals, doctors' offices, etc.) does not require the submission of proprietary information. The form contains a Privacy Act statement on page 4. The submitted applications are stored in a secure docket file room. They are only released to the public on request after screening out personal and proprietary information, if any. No files are maintained by name of individual.

(vii) None.

(viii) None.

3. Time Schedule for Information Collection and Publication

Applicants for new licenses or renewals of existing licenses will submit Form NRC-313M with the requested information. New applications may be submitted at any time. Renewal applications are required to be submitted every five years. Requests for additional information to complete or clarify the information submitted in the application or to rectify deficiencies in proposed programs would be issued as necessary. The NRC expects that an average of one additional information request per submittal will be needed, and that this request would normally be issued within three months of the initial submittal. Responses to requests for additional information would normally occur within two months, and the NRC would normally take appropriate licensing action within about one month of the availability of all required information.

4. Consultations Outside the Agency

There have been no consultations outside the agency since the initial GAO clearance of the form.

5. Estimate of Compliance Burden

It is estimated that approximately 500 applications will be submitted annually to NRC by applicants on Form NRC-313M.

Each application will require approximately two staff hours to prepare.

500 x 2 staff hours = a total annual burden for all applicants of 1,000 staff hours.

6. Sensitive Questions

None.

7. Estimate of Cost to Federal Government

The cost to the Federal Government is estimated to be approximately $320,000 annually.

FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION **APPLICATION FOR MATERIALS LICENSE – MEDICAL**	Approved: GAO R0557

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

TELEPHONE NO.: AREA CODE( ) ___ ___

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

2. PERSON TO CONTACT REGARDING THIS APPLICATION

TELEPHONE NO.: AREA CODE( ) ___ ___

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
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.)*

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 INTRACAVITARY 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

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

- ☐ 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

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)

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

(2) LICENSE FEE ENCLOSED: $ _____

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*

(2) TITLE

c. DATE

FORM NRC-313M (8-78)

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 Form NRC-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.

FORM NRC-313M-SUPPLEMENT A (8-78)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

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			
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

FORM NRC-313M-SUPPLEMENT B
(8-78)

U. S. NUCLEAR REGULATORY COMMISSION

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

STREET ADDRESS

CITY | STATE | ZIP CODE

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		
	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		
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

b. NAME OF INSTITUTION

c. MAILING ADDRESS

d. CITY

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE

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

8. DATE