

FORM NRC-313M

7-77

10 CFR 30

U.S. NUCLEAR REGULATORY COMMISSION

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. Mail two copies 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 NRC Materials License. A 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

Jose N. De Leon, M.D.
86 Georgetti St.
Rio Piedras, Puerto Rico 00925

TELEPHONE NO.: AREA CODE 809 767- 9873

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

02200
30-17134
L+L 19206

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Jose N. De Leon, M.D.
86 Georgetti St.-Rio Piedras, P.R.

TELEPHONE NO.: AREA CODE 809 767- 9873

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.)

Jose N. De Leon, M.D.

5. RADIATION PROTECTION OFFICER (Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience as in Supplement A.)

Jose N. De Leon, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ITEM	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 AND CARDIAC DYSFUNCTION		
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	X				

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. (Small sealed sources (up to 3m Ci) 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>Date: NOV 1 6 1979 Log: NRI PG 4 N.C. By: Brown Orig. To: [unclear] Action Compl: 11/14/79</p> <p>Applicant: [unclear] Check No: 545 Amount: \$190.70 Type of Fee: application Date Check Rec: NOV 1 6 1979 Received By: [unclear]</p> <p>01821</p>			

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7912030151

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

Submit a detailed description of all the information requested in Items 7 through 23. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right hand corner of each page. Two copies of each appended sheet should be submitted with the application.

7. MEDICAL ISOTOPES COMMITTEE.

- a. Committee's Duties and Responsibilities.
- b. Meeting Frequency.
- c. Name and Specialty of Each Committee Member.

8. TRAINING AND EXPERIENCE.

- a. Authorized User(s). *(Each physician must complete Supplements A and B.)*
- b. Radiation Safety Officer.
(Complete Supplement A, if other than a physician already listed.)

9. INSTRUMENTATION. *(List by manufacturer's name and model number.)*

- a. Survey Instruments.
- b. Dose Calibrator.
- c. Diagnostic Instruments.
- d. Other *(e.g. liquid scintillation counter, area monitor.)*

10. CALIBRATION OF INSTRUMENTS.

- a. Methods.
- b. Frequency.
- c. Standards (Radionuclide and Activity).

11. FACILITIES AND EQUIPMENT. *(Complete description and diagram.)*

12. PERSONNEL TRAINING PROGRAM AND FREQUENCY.

13. PROCEDURES FOR ORDERING AND RECEIPT OF RADIOACTIVE MATERIAL.

14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL.

15. GENERAL LABORATORY RULES FOR THE SAFE USE OF RADIOACTIVE MATERIALS.

16. EMERGENCY PROCEDURES, INCLUDING NAMES AND TELEPHONE NUMBERS OF PERSONNEL TO BE NOTIFIED.

17. AREA SURVEY PROCEDURES.

18. WASTE DISPOSAL PROCEDURES.

19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS.

- a. Procedures.
- b. Precautions.
- c. Personnel Instructions.

20. THERAPEUTIC USE OF SEALED SOURCES.

- a. Procedures.
- b. Precautions.
- c. Personnel Instructions.

21. PROCEDURES AND PRECAUTIONS FOR USE OF ¹³³XENON RADIOACTIVE GASES. *(e.g., xenon-133)*

22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS.

23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.B.

Element and Mass No.	Chemical and/ or Physical Form	Maximum Number of Millicuries of each form	Describe Purpose of Use
90-Sr.-90-Y.	Strontium titanate dis-	Maximum quantity of	Human use.
	pensed in a silver	90-Sr.-90-Y. is 150	
	matrix bonded to a	millicuries. Sealed	
	0.04 mm thick silver	source (Isotope Pro-	
	foil. Matrix hermetica-	ducts Labs, Model No.	
	lly sealed in titanium	BF 90 TI-150) contained	
	by fusion welding with	in Nuclear Associates	
	a window thickness of	Beta Therapy System	
	0.127 mm and a wall	Model 67-850.	
	thickness of 0.8 mm.		

THERAPEUTIC USE OF SEALED SOURCES.

a. Procedures: Treatment of superficial diseases of the eye.

b. Precautions:

1. The source should be stored in the case at all times other than during sterilization or actual treatment unless, an effective shield enclosure is employed.
2. The storage case should be locked at all times and secured in an enclosure to inhibit unauthorized removal or theft.
3. The lucite Beta shield should be positioned on the shaft as close to the source as possible during treatment to minimize scattered radiation angles.
4. Castroviejo Collimating Masks should be fitted and removed with the source facing away from the operator. The mask should be placed on a sterile towel over a firm work surface and the source capsule inserted into it, gripping the mask with the special forceps supplied. Reverse the procedure for removal. No sharp objects should be used near the source window.
5. The source capsule should be disinfected only by immersion in alcohol, using a small appropriately shielded container, to minimize radiation exposure and prevent damage to the source window.
6. In the event of apparent or probable damage to the source it should be placed in the storage case immediately. The storage case should be wrapped or placed in a plastic bag and secured. The cognizant radiation protection officer, regulatory agency, or supplier should be contacted immediately for consultation and action.
7. Routine wipe tests must be performed at 6-months intervals and maintain records. Withdraw the source from service if leak test results indicate any increase in detectable activity from that of previous leak tests.

c. Personnel instructions:

This item can only be handled personally by the owner, in this case by myself.

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED
IN ITEM 6B.

Procedures:

Treatment of superficial diseases of the eye.

Precautions:

1. The source should be stored in the case at all times other than during sterilization or actual treatment unless, an effective shield enclosure is employed.
2. The storage case should be locked at all times and secured in an enclosure to inhibit unauthorized removal or theft.
3. The lucite Beta shield should be positioned on the shaft as close to the source as possible during treatment to minimize scattered radiation angles.
4. Castroviejo Collimating Masks should be fitted and removed with the source facing away from the operator. The mask should be placed on a sterile towel over a firm work surface and the source capsule inserted into it, gripping the mask with the special forceps supplied. Reverse the procedure for removal. No sharp objects should be used near the source window.
5. The source capsule should be disinfected only by immersion in alcohol, using a small appropriately shielded container, to minimize radiation exposure and prevent damage to the source window.
6. In the event of apparent or probable damage to the source it should be placed in the storage case immediately. The storage case should be wrapped or placed in a plastic bag and secured. The cognizant radiation protection officer, regulatory agency, or supplier should be contacted immediately for consultation and action.
7. Routine wipe tests must be performed at 6-months intervals and maintain records. Withdraw the source from service if leak test results indicate any increase in detectable activity from that of previous leak tests.

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. OTHER <i>(Specify)</i>			

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. c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.	
MAILING ADDRESS			
CITY	STATE		

26. CERTIFICATE <small>(This item must be completed by applicant)</small>	
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, Part 30, 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 <small>(See Section 170.31, 10 CFR 170)</small> <div style="text-align: right; margin-top: 20px;"> <i>Lic P.R. 1963</i> </div>	b. APPLICANT OR CERTIFYING OFFICIAL <i>(Signature)</i> <div style="text-align: center; margin-top: 20px;"> </div>
(1) LICENSE FEE CATEGORY: Sr.-90- Ophthalmic applicator	(1) NAME <i>(Type of Print)</i> Jose N. De Leon, M.D. (2) TITLE Ophthalmologist 01821
(2) LICENSE FEE ENCLOSED: \$ <u>190.00</u>	c. DATE October 3, 1979

- c. Manufacturer will supply Leak Test Kit on a semi-annual basis.

(7-77)
10 CFR 30TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION PROTECTION OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION PROTECTION OFFICER

Jose N. De Leon, M.D.

2. STATE OR TERRITORY IN
WHICH LICENSED TO
PRACTICE MEDICINE
Puerto Rico

3. CERTIFICATION

SPECIALITY BOARD
ACATEGORY
BMONTH AND YEAR CERTIFIED
C

Not certified yet.

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4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING
ALOCATION AND DATE(S) OF TRAINING
B

TYPE AND LENGTH OF TRAINING

LECTURE/
LABORATORY
COURSES
(Hours)
CSUPERVISED
LABORATORY
EXPERIENCE
(Hours)
Da. RADIATION PHYSICS AND
INSTRUMENTATION

b. RADIATION PROTECTION

c. MATHEMATICS PERTAINING TO
THE USE AND MEASUREMENT
OF RADIOACTIVITY

d. RADIATION BIOLOGY

e. RADIOPHARMACEUTICAL
CHEMISTRY

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

Jose N. De Leon, M.D.

STREET ADDRESS

86 Georgetti

CITY

STATE

ZIP CODE

Rio Piedras

P. R.

00925

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 AND CARDIAC CONDITION		
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	320	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sr-90/ Y-90	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

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

During his residency training in ophthalmology (3 years) received about 200 hours in clinical radioisotope training, mainly in the application of Beta Radiation postoperatively for pterygia and for the up of these cases.

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

a. NAME OF SUPERVISOR

Guillermo Picó, M.D.

b. NAME OF INSTITUTION

Dept. of Ophthalmology, School of Medicine, Univ. of Puerto Rico, San Juan, Puerto Rico.

c. MAILING ADDRESS

Univ. de P.R., Recinto Ciencias Médicas, Dept. of Ophthalmology, Box 5067

d. CITY

San Juan, P.R., 00936

5. MATERIALS LICENSE NUMBER(S)

52-07636-02

6. PRECEPTOR'S SIGNATURE

Guillermo Picó

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

Guillermo Picó, M.D.

8. DATE

Oct. 23, 1979