NRC FORM 313M

(9-81) 10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Approved by OMB 3150-0041 Expires 9-30-86

INSTRUCTIONS -- Complete I terms 1 through 26 if this R 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 t	rements contains, Parts 19, 20	the applicant will re ned in Title 10, Code and 35 and the licens	of Sareguards, C.S. Nocean Ne ceive a Materials License. An I of Federal Regulations, Part 3 se fee provision of Title 10, Coo criate fee enclosed.	NRC Materials Lice 0, and the License	ense is issue e is subject ilations, Pai	ed in acc to Title et 170.	10.
1.a. NAME AND MAILING ADDRESS OF firm, clinic, physician, etc.) INCLUDE		T (institution,	1.b. STREET ADDRESS WILL BE USED (If				
Vicente J. Caride MD Dpt. Nuclear Medicin	e		Shoreline M		magin	ng ,	1,1.
Mospital of St.Raphael			6 Woodland Madison,Ct			X	23588
1450 Chapel St. New TELEPHONE NO. AREA CODE 12						98	-
 PERSON TO CONTACT REGARDING Vicente J. Caride Md TELEPHONE NO.: AREA CODE 503 	1		a. M NEW LICENSI b. AMENDMENT c. RENEWAL OF	TO LICENSE	NO	pproprie 3	ate item)
4. INDIVIDUAL USERS (Name individual supervise use of radioactive material, Co for each individual,) Vicente J. Caride Md Edward K. Prokop MD	mplete Suppl	lements A and B	5. RADIATION SAFETY as radiation safety office me of training and expensions.	r. If other than in ience as in Suppler	dividual us ment A.)	-	
6. a. RADIOACTIVE MATERIAL FO	ITEMS	MAXIMUM POSSESSION			MA		MAXIMUM POSSESSION
RADIOACTIVE MATERIAL LISTED IN:	DESIRED	LIMITS (In millicuries)	ADDITIONA	AL ITEMS:	DESI		LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES			OF HYPERTHYROIDIS		MENT		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED	PHOSPHORUS 32 AS S	POLYCYTHEN	MIA		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREAT-				
10 CFR 35.100, SCHEDULE A, GROUP I	11		MENT OF MALIGNANT EFFUSIONS. GOLD-198 AS COLLOID FOR INTRA-				
10 CFR 35.100,SCHEDULE A, GROUP IV	/	AS NEEDED	CAVITARY TREATME	ENT OF MALIG	NANT		
10 CFR 36.100, SCHEDULE A, GROUP V	,	AS NEEDED	OF THYROID CARCIN		MENT		
10 CFR 36.100, SCHEDULE A, GROUP V	(1		XENON-133 AS GAS O BLOOD FLOW STUDII FUNCTION STUDIES.				
6.b. RADIOACTIVE MATERIAL F calibration and reference standards	OR USES N	NOT LISTED IN d under Section 35	NITEM 6.a. (Sealed source 5.14(d), 10 CFR Part 35, a	es up to 3 mCi used and NEED NOT	for BE LISTE	ED.)	
ELEMENT AND MASS NUMBER	РН	CHEMICAL AND/OR YSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	- DESCR	IBE PUR	POSE	OF USE
Gadolinium -153	Gd	02 seale	ed 1,500 ea.	mc	conclus.	1 A	nalýsis
			Lunar Model GD	NO NO	R - 2	CEIV	
License Fee Information	on.		Biosources LTD 05-213A	81 23 24	4 PI	ED	16
on p.3	711			E	2		160

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INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

DEFENDE PERMITS ON

		T	GENERAL RULES FOR THE SAFE USE OF			
7. N	EDICAL ISOTOPES COMMITTEE		RADIOACTIVE MATERIAL (Check One)			
	Names and Specialties Attached; and	X	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. T	RAINING AND EXPERIENCE	X	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. 11	NSTRUMENTATION (Check One)	X	Appendix I Procedures Followed; or			
X	Appendix C Form Attached; or		Equivalent Procedures Attached			
	List by Name and Model Number	18.	WASTE DISPOSAL (Check One)			
10.	CALIBRATION OF INSTRUMENTS		Appendix J Form Attached; or			
X	Appendix D Procedures Followed for Survey Instruments; or (Check One)	X	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.	11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES			
X	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)			
X	Detailed Information Attached		Detailed Information Attached			
PROCEDURES FOR SAFELY OPENING PACKAGES 14. CONTAINING RADIOACTIVE MATERIALS (Check One)			22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS Detailed Information Attached			
21			PROCEDURES AND PRECAUTIONS FOR USE OF			
X	Appendix F Procedures Followed; or	100	RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b			
	Equivalent Procedures Attached	X	Detailed Information Attached			

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Page 2

		24. PERSONNEL MONITORII	NG DEVICES		
(Check	TYPE appropriate box)	SUPPLIER	EXCHANGE FREQUENCY		
	FILM	R.S.Landauer	Monthly		
a. WHOLE BODY	TLD	E.G. Idilialier	IOHCHI		
	OTHER (Specify)				
	FILM				
b. FINGER	TLD				
	OTHER (Specify)				
	FILM				
c. WRIST	TLD				
	OTHER (Specify)				
•		Type of the Appleton 3/2 Lote Check heard. Lote Completed 3/2 By: This	Vation 19/06		
LICODITAL		FOR PRIVATE PRACTICE APPLIC			
NAME OF	THE RESIDENCE AND ADDRESS OF THE PARTY OF TH	PATIENTS CONTAINING RADIOACTIV	b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.		
CITY	ADDRESS	STATE ZIP CODE	c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAU- TIONS TO BE TAKEN AND LIST AVAILABLE FIADIATION DETECTION INSTRUMENTS.		
		26. CERTIFICATE (This item must be completed by	applicant)		
conformity	with Title 10, Code of Fed	ng this certificate on behalf of the applicated and Regulations, Parts 30 and 35, and the best of our knowledge and belief.	nt named in Item 1a certify that this application is prepared in at all information contained herein, including any supplements		
		EE REQUIRED 0.31, 10 CFR 170)	b. APPLICANT OR CERTIFYING OFFICIAL (Signature)		
	isee section 17	231, 10 CFN 170)	Vicente J. Caride MD		
(1) LICENSE	FEE CATEGORY		(2) TITLE		
(2) LICENSE	FEE ENCLOSED S	580	c. DATE		

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 Farts 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.
- 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.

NRC FORM 313M (9-81) Dr. Caride and Dr. Prokop are currently authorized users for groups I, II, III under License #06-00200-03 Docket # 030-01238.

APPENDIX C

INSTRUMENTATION

	ey meters			
a .	Manufacturer's name:LUD	1.0.1		
	Manufacturer's model number:	end window pro	he	h ::o:lel 44-7
	Number of instruments available:			
	Minimum range:			
	Maximum range:			
١.	Manufacturer's name			
	Manufacturer's model number:			
	Number of instruments available	:		
	Minimum range :	_ in R/hr to	mR/hr	
	Maximum range:	mR/hr to	mR/hr	
	e calibrator			
Man	ufacturer's name			
Man	ufacturer's model number			
Nun	nber of instruments available.			
Inst	r iments used for diagnostic proced	ures		
		Manufactu	rer's	

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

CALIBRATION OF SURVEY INSTRUMENTS

Check appro	opriat	titems.							
X 1.	Survey instruments will be calibrated at least annually and following repair.								
× 2.									
	che is p	two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properlibrated when the instrument readings are within ± 10 percent of the calculated or known values for each point could be repaired, attached to the instrument, and used to interpret readings to within ± 10 percent. Also, when higher are not checked or calibrated, an appropriate precautionary note will be posted on the instrument							
3.		vey instruments will be calibrated							
<u>X</u>	4.	By the manufacturer							
	b .	At the licensee's facility							
		(1) Calibration source							
		Manufacturer's name							
		Model no. Activity in millicuries							
		Exposure rate at a specified distance							
		Accuracy Traceability to primary standard							
		(2) The calibration procedures in Section I of Appendix D will be used							
		(3) The step-by-step procedures, including radiation safety procedures, are attached.							
	c.	By a consultant or outside firm							
		(1) Name							
		(2) Location							
		(3) Procedures and sources							
		have been approved by NRC and are on file in License No							
		have been approved by an Agreement State; a copy of the Agreement State license, the procedures, and a description of the sources are attached, and the consultant's report will contain the information on							
		the attached "Certificate of Instrument Calibration."							
		the consultant's reporting form as attached.							
		are described in the attachment, and the consultant's report will contain the information on							
		the attached "Certificate of Instrument Calibration." the consultant's reporting form as attached.							

Except during source exchanges, the Gd-153 sealed source listed in Item 6b will be in the LUNAR DP3 Scanner. This Gd-153 source is contained in a lead lined source holder, LUNAR model DP3-A-SRC-0100-0. If necessary, the source will be temporarily equipped with a locking device to maintain the security of the source while in the scanner.

Each LUNAR bone mineral analyzer is installed by LUNAR personnel who provide one day of device specific training. The training includes source installation and exchanges, leak testing, scan operations, and data analysis and interpretation. The radiation safety training is performed with an empty source holder. LUNAR requires that the Radiation Safety Officer or a licensed individual user to be present for the instruction on their own. LUNAR'S procedure for installing and removing the source, found it the technical manuals, must be followed for all source exchanges.

PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY OF RADIOACTIVE MATERIAL

- The Supervisory Nuclear Medicine Technologist will
 place all orders for radioactive materials and will ensure
 that the requested materials and quantities are authorized by the license and that possession limits are not
 exceeded.
- A system for ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of the following.
 - a. Ordering of routinely used materials
 - Written records that identify the isotope, compound, activity levels, and supplier, etc., will be used.
 - (2) The written records will be referenced when opening or storing radioactive shipment.
 - Ordering of specially used materials (e.g., therapeutic uses)

- A written request* will be obtained from the physician who will perform the procedure.
- (2) Persons ordering the materials will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.
- (3) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.
- It is essential that written records^{*} be maintained for all ordering and receipt procedures.

In the case of special orders, the physician's written request and appropriate shipping/receipt records will be referenced and the dose assayed prior to its administration.

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

- Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205(a)(1) and (c)(1) of 10 CFR Part 20 (more than 20 Cl for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(s) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 µCi/100 cm2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).
- For all packages, the following additional procedures for opening packages will be carried out:
 - a. Put on gloves to prevent hand contamination.
 - Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.
 - c. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If >10 mR/hr, stop procedure and notify Radiation Safety Officer.
 - Measure surface exposure rate and record. If >200 mR/hr, stop procedure and notify Radiation Safety Officer.
 - e. Open the package with the following precautionary steps:
 - Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.

- (2) Open inner package and verify that contents gree with those on packing slip. Compare requisition,* packing slip, and label on bottle.
- (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).
- (4) Check also that shipment does not exceed possession limits.
- f. Wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., μCi/100 cm², etc.). Check wipes with a thin-end-window G-M survey meter, and take precautions against the spread of contamination as necessary.
- g. Monitor the packing material and packages for contamination before discarding.
 - (1) If contaminated, treat as radioactive waste.
 - (2) If not contaminated, obliterate radiation labels before discarding in regular trash.
- Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Record" (see next page) or a form containing the same information.

In the case of special orders (e.g., therapy doses), also compare with physician's written request.

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

- Wear laboratory costs or other protective clothing at all times in areas where radioactive materials are used.
- Wear disposable gloves at all times while handling radioactive materials.
- Monitor hands and clothing for contamination after each procedure or before leaving the area.
- 4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well-being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).
- a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
 - Do not store food, drink, or personal effects with radioactive material.
- a. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10 percent.
 - b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activ-

ity vs. the order written by the physician who will perform the procedure.

- 7. Wear personnel monitoring devices (film badge or TLI)) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.
- Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.
- Dispose of radioactive waste only in specially designated and properly shielded receptacles.
- 10. Never pipette by mouth.
- Survey generator, kit preparation, and injection areas
 for contamination after each procedure or at the end
 of the day. Decontaminate if necessary.
- Confine radioactive solutions in covered containers
 plainly identified and labeled with name of compound,
 radionuclide, date, activity, and radiation level, if
 applicable.
- Always transport radioactive material in shielded containers.

EMERGENCY PROCEDURES

Minor Spills

- NOTIFY: Notify persons in the area that a spill has occurred.
- PREVENT THE SPREAD: Cover the spill with absorbent paper.
- CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.
- SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.
- REPORT: Report incident to the Radiation Safety Officer.

Major Spills

- CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.
- PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

- SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
- CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.
- CALL FOR HELP: Notify the Radiation Safety Officer immediately.
- 6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

 Vicente J.

RADIATION SAFETY OFFICER: Caride, M. P. OFFICE PHONE: 789-3134
HOME PHONE: 397-3972

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER: Edward K. Prokop, M.D.

Office Phone: 789-3135 Home Phone: 288-7012

The appropriate information for your facility should be supplied in these blanks when posting these procedures or submitting them with the application.

AREA SURVEY PROCEDURES

Sealed sources used in LUNAR bone mineral analyzers will be leak tested for removable contamination every six months.

- 5. A permanent record will be kept of all survey results, including negative results. The record will include:
 - Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies.
 - b. Name of person conducting the survey.
 - Orawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
 - d. Measured exposure rates, keyed to location on the drawing (point out sates that require corrective action).
 - Detected contamination levels, keyed to locations on drawing.
 - f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels of exposure rates after corrective action, and any appropriate comments.
- Area will be cleaned if the contamination level exceeds 200 cpm/100 cm².

The depleted sealed source will be returned to the manufacturer for disposal. The manufacturer will be notified of the pending shipment and the anticipated delivery date. In the event the manufacturer is no longer in business, or for other reasons can not accept the source, an alternative waste disposal will be sought.

LUNAR has engineered their bone mineral analyzers to include safety precautions against the accidental opening of the leaded shutter shielding the radioactive source.

The static state of the solenoid controlling the shutter is closed. A +12V dc signal must be applied to the circuit for any solenoid action, hence, disconnection of the AC power cable will de-energize the circuit and close the shutter. Disconnection of the interface cable will remove the "solenoid control" signal and de-energize the solenoid therefore closing the shutter.

Sealed sources used in LUNAR bone mineral analyzers will be leak tested for removable contamination every six months.

Nate & Regime? I don't believe the attached controls replace the correct applicant / address.

I think \$\frac{1}{2} \text{ should be} for the addresses and medical grups lected in alter & glack app. (But you know /dys!!) Glende

"OFFICIAL RECORD COPY" MLIA

2/28/86. In Talking with Der. Edward K. Brokop. these will be 2 separate fecences erested at 2 separate facilities. (119556+ Thanks Claire Bury M113 "OFFICIAL BEGOND COPY"



NUCLEAR REGULATORY COMMISSION WASHINGTON, D. C. 20555

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BETWEEN: William O. Miller, Chief

License Fee Management Branch

Office of Administration

Regional License Section Material Licensing Branch

FCMS, Office of Nuclear Material

Safety & Safeguards

1	T	~	-	KI	C	-	CCC	TRANCMITTAL	
L	1	6	-	i¥	2	-	FEE	TRANSMITTAL	

LIC	ENSE FEE TRANSMITTAL		
Α.	REGION		
1.	A.	rile MD Vu	
	Applicant/Licensee: (a	na mp, on	cente .
	Application Dated:	2/28/86(rec'd)
	Control No.:	119536	
	License No.:		
2.	FEE ATTACHED		
	Amount:		
	Check No.:		
3.	COMMENTS		
		Signed	
		Date	
	LICENSE FEE MANAGEMENT BRANCH		
1.	Fee Category and Amount:	7e (\$580)	
2.	Correct Fee Paid. Applicatio	n may be processed for:	
	Amendment		
	Renewal		
	License		10