

EXHIBIT A

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 Metropolitan Medical Center 900 South Eighth Street Minneapolis, MN 55404 TELEPHONE NO.: AREA CODE (612) 347 4187		1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (If different from 1.a.) INCLUDE ZIP CODE <p style="text-align: center;">same</p>	
2. PERSON TO CONTACT REGARDING THIS APPLICATION Joseph R. Giganti, Ph.D. Radiation Safety Officer TELEPHONE NO.: AREA CODE (612) 347 4187		3. THIS IS AN APPLICATION FOR: (Check appropriate item) a. <input type="checkbox"/> NEW LICENSE b. <input checked="" type="checkbox"/> AMENDMENT TO LICENSE NO. 22-13859-01 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.)		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.) <p style="text-align: center;">Joseph R. Giganti, Ph.D.</p>	
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
I-125	ion exchange (AECL C234)	200 mCi. each (250 mCi total)	Bone mineral Scanner radiation source.
Gd-153	GdO ₂ sealed source	1000 mCi. each (1300 mCi. total)	Bone mineral Scanner radiation source.

 FORM NRC-313M
 (8-78)

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 REG3 LIC30
 22-13859-01 PDR

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REGION III

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	FILM	R.S. Landauer (no changes)	
	TLD		
	OTHER (Specify)		
b. FINGER	FILM		
	TLD	R.S. Landauer (no changes)	
	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		b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.
NAME OF HOSPITAL		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 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.

a. LICENSE FEE REQUIRED (See Section 170.31, 10 CFR 170)	b. APPLICANT OR CERTIFYING OFFICIAL (Signature)
(1) LICENSE FEE CATEGORY: 7 A	(1) NAME (Type of Print) Joseph R. Giganti, Ph.D.
(2) LICENSE FEE ENCLOSED: \$ 40.00	(2) TITLE Radiation Safety Officer
	c. DATE June 7, 1985

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REGION III

CONTROL NO. 79163

Applicant: June-16-1985
Check No. 018440
Amount/Fee Category: \$40.00
Type of Fee: License
Date Check Rec'd: 6/20/85
Received By: jacquie

Metropolitan Medical Center

Byproduct Materials License Amendment
Date: June 6, 1985

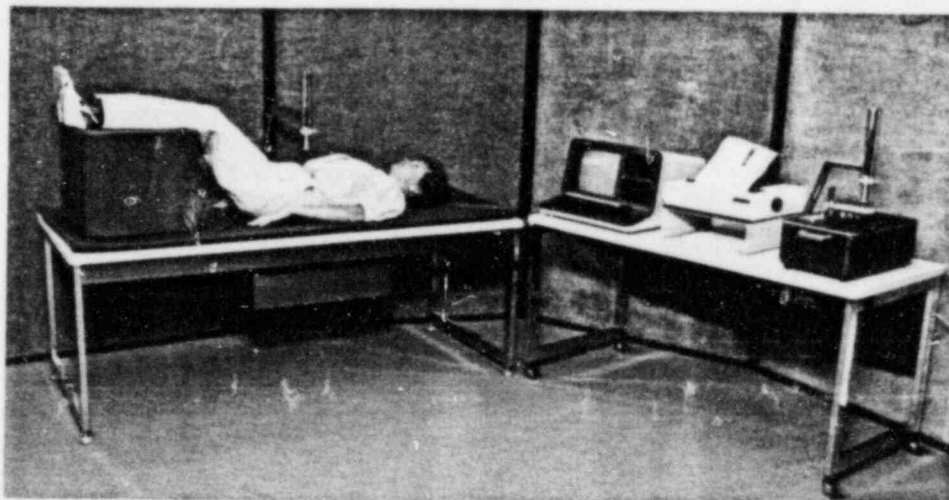
NRC form 313M, item 23. Procedures and precautions for use of
Radioactive materials specified in item 6.b:

The sources listed under item 6b are sealed sources for use in a bone mineral scanner device. The device is made by Lunar Radiation Corp designated their Model DP3. A brochure describing this unit is attached. The sources will be received from their manufacturer using common carriers. The packages will be surveyed for external exposure and leakage per our procedures already in your file. Records of these tests will be kept for commission inspection. The decayed source will be removed strictly following manufacturer procedure by a hand and body monitored technician. The newly obtained source will be replaced in the machine. Finally the decayed source will be placed in the shipping container and returned to the manufacturer for disposal. The requested maximum authorization covers two sources which would be on site during the source change operation. Before returning the sources, the shipping container would be monitored for external exposure and leakage of source material. External exposure monitoring would be done with our calibrated Victoreen Model 498 /491-30 and leakage would be monitored by taking wipe samples and counting them in our Ludlum/Picker well scintillation detector and scaler. An I-125 leak test standard is available to insure system sensitivity.

The entire system will be assigned a room in the department of nuclear medicine which has restricted access. The room will be locked when no technician or knowledgeable person is available.

LUNAR RADIATION CORPORATION

DP3 SPINE/FEMUR SCANNER



DESCRIPTION

The DP3 Spine/Femur scanner is the most widely used system for monitoring the axial skeleton in the world today. Used by nearly 90% of existing U.S. facilities, the DP3 has set the standard for dual-photon measurements of the spine and proximal femur and is particularly well-suited for diagnosis and monitoring of osteoporosis.

COMPONENTS

- Rectilinear Scanner Module
- Scanner Table
- Computer Console Table
- Calibration Standard
- Epson FX-80 Printer (optional)
- SP2 Forearm Scanner (optional)
- Northstar Advantage Computer
 - (640 X 240 pixel display)
 - dual DSDD disk drives; 27 scans/diskette

SOFTWARE

LUNAR'S sophisticated software makes measurements easy and precise. Automated analysis ensures fast results, but overrides allow the operator to make adjustments if necessary. Correction factors incorporated in the software make measurements independent of tissue cover or position of the bone in the beam path. Calibration to standards allows utilization of existing normal databases and inter-unit comparisons. Intelligent software locates bones of interest and tracks them eliminating positioning problems and dependence on large scan areas. This technique gives lower patient radiation dose, max-

imum precision, high anatomical resolution, and fast scan times. Scan programs for lumbar spine and proximal femur are standard (typical scan time is 15 minutes). Programs feature automatic location of baselines, bone edges and regions of interest.

RESULTS

Results are graphically displayed, stored on diskette for later analysis, and printed out. Bone mineral content (g), area (cm²), and density (g/cm²) are calculated for each region of interest. For the lumbar spine values are given for each vertebra and for various combinations. For the proximal femur values are given for the femoral neck, Wards triangle and the trochanter. All data are compared to a normal U.S. database after adjusting for age, body size, sex and race.

RADIATION/LICENSING

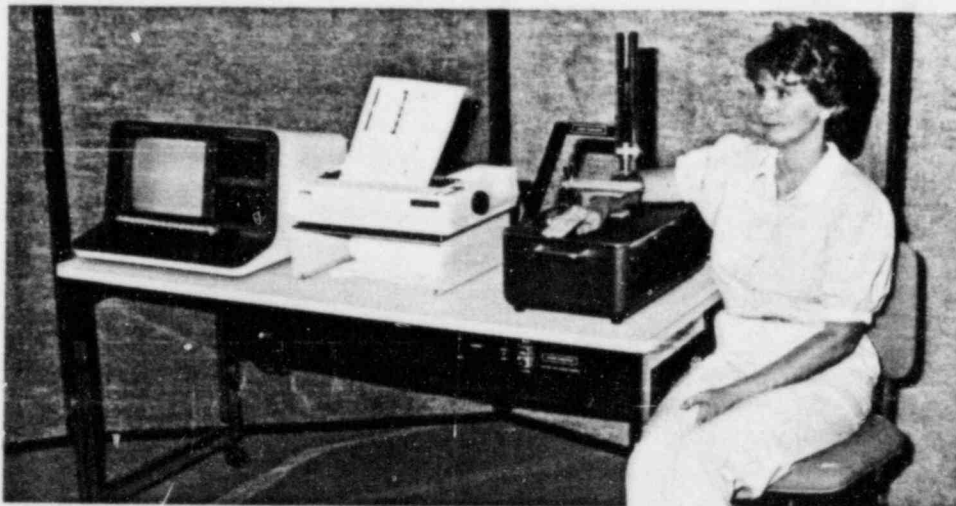
- NRC or state licensing required for a 1 Ci sealed source of 153-Gd.
- NRC device registration number NR-430-D-101-S
- FDA 510K approval (K802180A)
- Dose to patients — under 12 mrem
- Dose to operator — < 0.1 mrem/day
- Source life — 12-18 months typical; up to 24 months

POWER/SPACE

- 110V/60Hz or 220V/50Hz, 630 W
- Single phase, grounded
- Recommended space: 8' x 10'

LUNAR RADIATION CORPORATION

SP2 RECTILINEAR FOREARM SCANNER



DESCRIPTION

The SP2 Rectilinear Forearm Scanner is the industry's most advanced system for determining bone mineral content using single photon absorptiometry (^{125}I). The SP2 is a completely automated scanner that indicates bone density on infants, adults and small animals. The rectilinear scan used by the SP2 allows bone width, distance between bones or anatomical landmarks to serve as the basis for accurate repositioning. Rectilinear scanning minimizes anatomical variation which is the major source of precision error. Scans can be done at the usual shaft and distal sites and at the exclusive ULTRASDISTAL site (75% trabecular bone).

COMPONENTS

- Rectilinear Scanner Module
- Scanner Software
- Calibration Standard
- Tissue Equivalent Bolus
- Epson FX-80 Printer (optional)
- Computer Console Table
- Northstar Advantage Computer
 - (640 X 240 pixel display)
 - dual DSDD disk drives; 55 scans/diskette

SOFTWARE

LUNAR'S sophisticated software makes system operation easy by using menus and

operator prompting. Scan procedures are completely automated but allow for operator override to ensure the most precise results. Total scan time is approximately 10 minutes. Quality control programs are included.

RESULTS

Results are graphically displayed, stored on diskette for later analysis, and printed out. Bone mineral content (g), bone width (cm) and BMC/W (g/cm^2) are calculated for each site. All data are compared to a normal U.S. database after adjusting for age, body size, sex and race.

RADIATION/LICENSING

- NRC or state licensing required for a 200 mCi sealed source of ^{125}I
- NRC registration number NR-430-D-102-S
- FDA 510K approval (K802181A)
- Dose to patients — typically under 10 mrem
- Dose to operator — < 0.1 mrem/day
- Source life — 6 months
- Source capsule C324 from Atomic Energy of Canada

POWER/SPACE

- 110V/60Hz or 220V/50Hz, 575 W
- Single phase, grounded
- Recommended space: 6' x 6'

LUNAR RADIATION CORPORATION

The leader in bone measurement

916 WILLIAMSON STREET
MADISON, WI 53703
(608) 258-8545

CONTROL NO. 7 9 1 6 3



Metropolitan Medical Center
A HealthOne Company

900 South Eighth Street
Minneapolis, Minnesota 55404
612/347-4444

PRESORTED
FIRST CLASS



U.S. Nuclear Regulatory Commission
Region III
Licensing Branch
799 Roosevelt Road
Glen Ellyn, IL 60137



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