



July 19, 1985

U. S. Nuclear Regulatory Commission  
Region III  
799 Roosevelt Road  
Glen Ellyn, Illinois 60137

Reference: License No. 13-16457-01

Gentlemen:

Please accept this letter as our request to amend the above license.

The amendment requested is to allow for the possession and use of Gd-153 sealed sources in a bone mineral analyzer. Given in Attachment 1 are necessary additions to our renewal application for Items 4, 6b, 8, 11, 12, 15, 17 and 18.

Also, we wish to add one new authorized user and delete three others from our license. Please refer to Attachment 2 for details.

We hope this letter with attachments is satisfactory. Any questions about the amendment can be directed to Jack Weinbaum, M.D., R.S.O. at (812) 238-7542 or Gerald Wicks at (312) 564-3330.

A check for 120.00 is enclosed as amendment filing fee.

Sincerely,  
Union Hospital

*Frank Shelton*  
Frank Shelton  
Administrator

FS:mem  
Enclosure

8509160351 850809  
REG3 LIC30  
13-16457-01 PDR

*July 23<sup>rd</sup>*

Applicant	123113
Check No.	7120
Amount/Fee Category	7E
Type of Fee	amend
Date Check Rec'd	7/31/85
Received By	<i>[Signature]</i>

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U.S. N.R.C.  
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**AUTHORIZED USERS AND TRAINING AND EXPERIENCE  
FOR THE BONE MINERAL ANALYZER**

The following physicians will be using the Lunar DP3 Spine/Femur Scanner:

Jack G. Weinbaum, M.D.  
James B. Kho, M.D.  
M. Bashir Kashlan, M.D.

For training and experience of these physicians, please refer to License No. 13-16457-01. Furthermore, these physicians will receive training from the Lunar Radiation Corp.

Each Lunar Bone Mineral Scanner is installed by a qualified expert who will provide two days of installation and training. This training covers source installation, wipe testing, scan operations, and data analysis and interpretation. The institution's Radiation Safety Officer must be present for instruction on source replacement and wipe testing.

# RADIOACTIVE MATERIAL FOR MEDICAL USE

[Not Listed in Item 6a]

<u>Element and Mass Number</u>	<u>Chemical / Physical Form</u>	<u>Distributor &amp; Model No.</u>	<u>Activity</u>
Gd-153	Gd $O_2$ (Sealed)	Gulf Nuclear, Model GD-1	1000 mCi each 2000 mCi total*
or Gd-153	Gd $O_3$ (Sealed)	Dupont - New England Nuclear Model No. NER-430 or NER-431	1000 mCi each 2000 mCi total*

**\*Note:** For continuity of use, the total amount listed includes the summed activity of a new source and decayed sources. (Useful life of one source is 12 to 18 months according to the manufacturer.) Old, unusable sources will either be held for decay to background radiation levels in the Radioactive Decay Area or returned to the source distributor.

The Gd-153 source will be used in a bone mineral analyzer sold by Lunar Radiation Corp. of Madison, Wisconsin. The model number is DP-3 and the NRC device registration number is NR-430-D-101-S.

The Gd-153 sealed source is sold by:

1. Gulf Nuclear Inc.  
202 Medical Center Boulevard  
Webster, Texas 77598  
Phone: (713) 332-3581
2. New England Nuclear - Dupont  
601 Treble Cove Road  
North Billerica, Massachusetts 01862  
Phone: (800) 225-1572

## FACILITIES AND EQUIPMENT

The bone mineral analyzer will be located in the Nuclear Medicine Department in the Imaging Section.

Old, unusable Gd-153 sources will be stored in a lead container in the department's Radioactive Decay Area.

ITEM 11 (7/85)

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# LUNAR RADIATION CORP.

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## DP3 SPINE/FEMUR SCANNER and SP2 FOREARM SCANNER SPECIFICATIONS

### Computer

NorthStar Advantage

Dimensions: 28x51x32cm (20kg)

Processor: Z80A CPU and INTEL 8035; option IBM compatible

Display: 28cm diagonal P31 Phosphor; 1920 character (24 lines x 80 characters); graphics 240x640 pixels bit-mapped; screen dump to printer

Disks: Two 5-1/4" floppy diskette drives (double-sided, double density); 360K byte per diskette (10 sector); holds 25 spine or femur scans or 55 forearm scans per diskette

### Nuclear Instrumentation

High voltage: Programmable 600 to 1600V

Amplifier: High-speed (0.25 microsec shaping time)

Dual-channel analyzer: Low-drift fast analyzers

Dual-scalers: 10 MHz scalers (10-bit)

Timer: Crystal-controlled programmable

Detector: Collimated NaI (Tl) scintillation detector with Bialkali Cathode

### Motors and Control

Motors: 4-phase stepping motors

Control: Programmable controller; menu-driven step interval and speed

### Scan Table (for DP3)

Dimensions: 183 x 81 x 69cm (50kg)

Materials: 2.5 x 5cm chrome plated steel legs; laminate covered wood top

### Console Table (for both DP3 and SP2)

Dimensions: 152 x 76 x 69cm (30kg)

Materials: 2.5 x 5cm chrome plated steel legs; laminate covered wood top

### Scanner Mechanism

DP3-Dimensions: 60 x 60 x 25cm metal enclosure below table (30kg)

SP2-Dimensions: 56 x 54 x 46cm metal enclosure

Source access: Through locked table top

### Software

Operating system, graphics and BASIC are standard.

Compiled programs include: spinal scanning, femoral scanning, quality control; reanalysis of data from diskette

### Warranty

Ninety day complete parts and labor coverage warranty. One-year parts warranty on Lunar Radiation components (scanner and counting electronics).

### Service Contracts

Extension of the complete warranty service can be obtained under a service contract. Service contracts provide for the continued operation of your systems at a predictable cost. Benefits include one-day replacement service in case of failure and on-site service if necessary.

### Radionuclide sources

$^{153}\text{Gd}$  (1 Ci) sources are supplied by Gulf Nuclear of Webster, Texas (713-332-3581) for approximately \$6700 and can be used for 12-18 months.

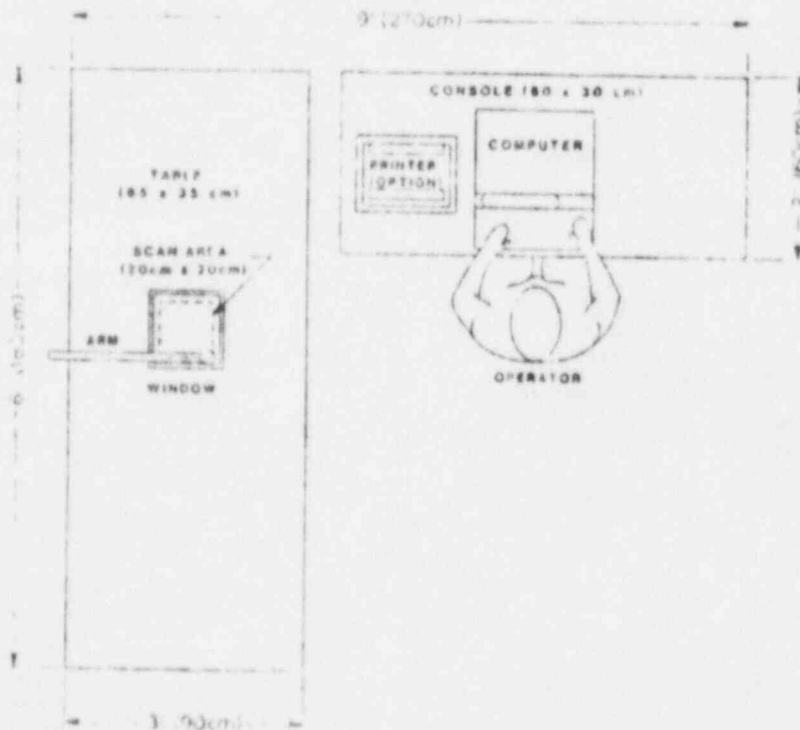
$^{125}\text{I}$  sources (200mCi) are supplied by Atomic Energy of Canada, Ltd. (613-592-2790, ext. 2048) for about \$600 and can be used for 6 months.

N.R.C. Device Registration: DP3 NR-430-D-101-S, SP2 NR-430-D-102-S. 8-hours training required for license.

### Delivery

30 days ARO.

### System Configuration (typical)



**LUNAR RADIATION CORPORATION**

916 Williamson Street—Madison, Wisconsin 53703

(608) 260-8545

**PERSONNEL TRAINING PROGRAM  
FOR THE BONE MINERAL SCANNER**

The technologist(s) will be instructed in the use of the Lunar DP-3 Spine/Femur Scanner and the radiation safety aspects of the Gd-153 sealed source. The instructions will be provided by a representative of the Lunar Radiation Corp., and will include the configuration of the source, safe removal of the source, safe storage of the source, the installation of the source and wipe testing of the source.

**GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIALS**

**FOR THE BONE MINERAL SCANNER**

Operating instructions given by Lunar Radiation Corp. for the DP-3 Spine/Femur Scanner (NRC device Registration No. NRC-430-D-101-S) will be followed.



**AREA SURVEY PROCEDURE**  
**FOR THE BONE MINERAL SCANNER**

The DP-3 Spine/Femur Scanner from Lunar Radiation Corp. containing the Gd-153 sealed source will be surveyed weekly using a low-level GM survey meter on contact with the external surface of the source housing and at three feet from the source housing location. Results will be recorded.

## WASTE DISPOSAL

Gd-153 sealed sources received by Gulf Nuclear Corp. or Dupont-New England Nuclear, will either be held for decay to background radiation levels or returned to the source distributor.

A low-level open window survey meter probe will be used to survey the unshielded Gd-153 sealed source(s) prior to disposal by bringing the probe into contact with the Gd-153 source(s). If the unshielded Gd-153 sealed source(s) survey results are equal to background radiation levels in an unrestricted area, the source(s) will be disposed. DOT and NRC regulations will be followed if the sources are returned to the distributor. Records of source disposal or return will be kept.

## ATTACHMENT 2

We wish to have George H. Kinnibrew, Jr. M.D. approved for Groups I, II, III and Xenon-133, and for Group IV use of I-131 for hyperthyroidism and cardiac dysfunction. Dr. Kinnibrew's preceptorship forms are attached. Dr. Kinnibrew is also listed as an authorized user on License No. 12-14142-01 at Paris Community Hospital, Paris, Illinois for Groups, I, II and III.

We also wish to have the physicians listed below deleted from our license as authorized users:

1. M. V. S. Raju, M.D.
2. Leon L. Blum, M.D.
3. Merry Lee Obetz, M.D.

(7/85)

CONTROL NO. 7 9401

(8-78)

# TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

George H. Kinnebrew, Jr., M.D.

2. STATE OR TERRITORY IN  
WHICH LICENSED TO  
PRACTICE MEDICINE

Indiana

## 3. CERTIFICATION

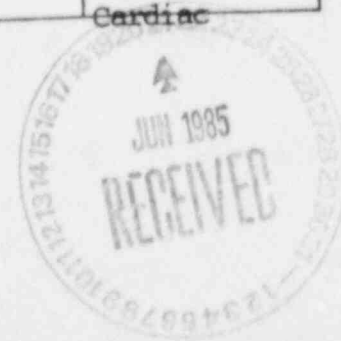
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology- Board Eligible	Diagnostic Radiology	

## 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	Youngstown Hospital Assoc. & St. Elizabeth Hosp. Med. Ctr. 7/79-6/83	100	10
b. RADIATION PROTECTION	Same as (a)	20	10
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Same as (a)	10	10
d. RADIATION BIOLOGY	Same as (a)	40	
e. RADIOPHARMACEUTICAL CHEMISTRY	Same as (a)	10	10

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I 131	100 uci	St. Elizabeth Hospital Medical Center, Youngs- town, Ohio. Youngs- town Hospital Association Youngstown, Ohio	January 1, 1982- March 31, 1982 During residency training.	Dx
I 131	15-200 mci			Rx
Yb169	1.5-6.0 mci			Cisternogram
I 131	500 uci			Renogram
GA67	5-45 mci			Tumor & abscess
Xe133	20-100 mci			Ventilation
Il25	5-15 mci			Fibrinogen
P32	5-15 mci			Rx
Tl201	2.0-6 mci			Cardiac



## 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			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.
FULL NAME George H. Kinnebrew, Jr., M.D.			
STREET ADDRESS 2052 S. Raccoon Rd., Apt. 12			
CITY Youngstown	STATE Ohio	ZIP CODE 44515	

## 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	170	Most of these numbers were acquired during the Nuclear Medicine rotation from Jan- uary 1982 through March, 1982.
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES	10	
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS	46	
I-131	THYROID IMAGING	10	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY	8	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	30	
OTHER	Renal imaging	20	
Tc-99m	BRAIN IMAGING	74	
	CARDIAC IMAGING	227	
	THYROID IMAGING	170	
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING	10	
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	383	
	LUNG IMAGING	133	
	BONE IMAGING	366	
OTHER	Tumor Imaging	91	

# 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	2	
P-32 (Colloid)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	2	
	TREATMENT OF HYPERTHYROIDISM	15	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
	TELETHERAPY TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	5	
Sn-113/ In-113m	GENERATOR N/A		
Tc-99m	REAGENT KITS	5	
Other			

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

January 1982 through March 1982--500 Total Number Hours

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

a. NAME OF SUPERVISOR

Clayton A. Hixson, M.D.

b. NAME OF INSTITUTION

St. Elizabeth Hospital Medical Center

c. MAILING ADDRESS

1044 Belmont Avenue

d. CITY

Youngstown, Ohio 44504

5. MATERIALS LICENSE NUMBER(S)

34-01131-01

### 6. PRECEPTOR'S SIGNATURE

Clayton A. Hixson M.D.

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

Clayton A. Hixson, M.D.

### 8. DATE

May 9, 1983

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