NEC 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 Items 1 through 26 if this & 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 License is subject to Title 10.

Code of Federal Regulations license fee category should b	Parts 1	9.20 4	end 35 and the licens	e fee provision of Title 10, Co	de of Federal Regul	etions, Part	170.	The
1.a. NAME AND MAILING ADDRESS OF APPLICANT (institution, firm, clinic, physician, etc.) INCLUDE ZIP CODE			1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (If different from 1.4) INCLUDE ZIP CODE					
LAURA LESPIEP-DEXTER, M.D.			BUILDING FRANCISCO RODRIGUEZ TORRES					
BOX 2810			POAD NO. 2 KM 11.2					
BAYAMON, PUERTO RICO 00621			BAYAMON, PUERTO RICO 00621					
TELEPHONE NO. AREA CODE \$09	1 78	87	9353					
2 PERSON TO CONTACT REGARDING	THIS A	PPLIC	CATION	3. THIS IS AN APPLIC		Check sop	ropri	ate item)
LAURA LESPIER-DEXTEP. M.D.			A NEW LICENSE  D AMENDMENT TO LICENSE NO.					
TELEPHONE NO. AREA CODE 1809			9353	G. ARNEWAL OF LICENSE NO.				
4. INDIVIDUAL USERS (Name individuals	s who	will u	se or directly	5. RADIATION SAFET	Y OFFICER (RSC	O) (Name	of pe	rson designated
supervise use of radioactive material, Conforeach individual, )	npie te S	ripple	ments A and B	as radiation safety officer. If other than individual user, complete resu- me of training and experience as in Supplement A.)				
LAURA LESPIER-DEXTER	, 11.1	Ρ.		LAURA LESPIER-DEYTFR, M.D.				
6. RADIOACTIVE MATERIAL FO	R MED	DICA	L USE	· •				
	ITEM		MAXIMUM POSSESSION			MARI		MAXIMUM POSSESSION
RADIOACTIVE MATERIAL DESI		RED LIMITS		ADDITIONAL ITEMS:		DESIRE	D	LIMITS
		"X"	(In millicuries)	IODINE-131 AS IODID	E EOR TREATM		X"	(In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES				OF HYPERTHYROIDIS		ENI		
10 CFR 35, 100 SCHEDULE A GROUP I	O CFR 35,100 SCHEDULE A, GROUP I AS NEEDED		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 C	THE RESIDENCE AND A SECURITY OF THE PROPERTY O			
10 CFR 35,100, SCHEDULE A, GROUP III				PHOSPHATE FOR INTRACAVITARY TREAT- MENT OF MALIGNANT EFFUSIONS.				
TO SECOND CONTENT OF A CHOOP III				GOLD-190 AS COLLOID FOR INTRA-				
10 CFR 35.100 SCHEDULE A, GROUP IV	EDULE A. GROUP IV AS NEEDED		AS NEEDED	CAVITARY TREATMENT OF MALIGNANT EFFUSIONS.				
				IODINE-131 AS IODIDE FOR TREATMENT				
10 CFR 35 100, SCHEDULE A, GROUP V			AS NEEDED	OF THYROID CARCINOMA				
10 CFR 35 100 SCHEDULE A, GROUP VI				SENON-133 AS GAS O BLOOD FLOW STUDIES FUNCTION STUDIES				
6.b. RADIOACTIVE MATERIAL FO	R USE	ES N	OT LISTED IN	ITEM 6.a. (Sealed source 14(d), 10 CFR Part 35 a	s up to 3 mCi used for	or E LISTED		
ELEMENT AND MASS NUMBER	T	C	HEMICAL AND/OR	MAXIMUM NUMBER OF MILLICURIES			********	
ELEMENT AND MASS NOMBER			SICAL FORM	OF EACH FORM	DESCRI	BE PURPO	DSE (	DF USE
Iodine-125		Sealed Source		2 sources/no	Norland B	one De	sit	ometer
				one source to				N2780 Module
				exceed 400 mCi				
(Source Model No. AECL C-			C-234				-10	1
and source holder Model (			-D-102-E	Digner 1000		1/3	1	
See NRC Registration Sheet NR-482-D-102-F, 1		August 1983 5/5/904		04				
8710070207 870427					7	4 '		
NRC FOR! REG2 LIC30 52-24904-01	PDR						-	fit is a second

INFORMATION	REQUIRED	FOR ITEMS 7	THROUGH 23
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For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revnumber and date of the referenced guide: Regulatory Guide 10.8 , Rev Date:	

7.	MEDICAL ISOTOPES COMMITTEE	13.	GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One)
	Names and Specialties Attached; and	1	Appendix G Rules Followed; or
-	Duties as in Appendix B; or (Check One)	X	Equivalent Rules Attached
	Equivalent Duties Attached	16.	EMERGENCY PROCEDURES (Check One)
8.	TRAINING AND EXPERIENCE Item 8	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. 1	NSTRUMENTATION (Check One)	X	Appendix I Procedures Followed; or
	Appendix C Form Attached; or		Equivalent Procedures Attached
Х	List by Name and Model Number	18.	WASTE DISPOSAL (Check One)
10.	CALIBRATION OF INSTRUMENTS	X	Appendix J Form Attached; or
	Appendix D Procedures Followed for Survey Instruments, or		Equivalent Information Attached
X	Equivalent Procedures Attached; and	19.	THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)
	Appendix D Procedures Followed for Dose Calibrator; or	1	Appendix K Procedures Followed; or
or standar again	Equivalent Procedures Attached (Check One)		Equivalent Procedures Attached
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
Х	Description of Training Attached		Equivalent Procedures Attached
3.	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		22.	PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS
	(Check One)		Detailed Information Attached
Х	Appendix F Procedures Followed; or	23.	PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.6

(Check a	TYPE	W. V. W. W. W. W.		
	ppropriete box!	SUPPLIER		EXCHANGE FREQUENCY
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#### PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Fublic 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 record, 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 PURPOJE(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
  AMFORMATION 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

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## AUTHORIZED USER OR RADIATION SAFETY OFFICER

LAURA LESPIER-DEXTER, M.D.	PRACTICE MES	2 STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE		
The second secon	3. CERTIFICATION			
SPECIALTY BOARD	CATEGORY	MONTH AND YE		
AMERICAN BOARD OF INTERNAL MEDICIN	E DIPLOMATE	JUNE - 197	5	
MILLICAN BOARD OF NEPHROLOGY	DIPLOMATE	JUNE - 197	8	
4. TRAINING RECEIV	ED IN BASIC RADIOISOTOPE HANDL	ING TECHNIQUES		
		TYPE AND LENG	TH OF TRAINING	
FIELD OF TRAINING	LOCATION AND DATE (S) OF TRAIN	LECTURE/ LABORATORY COURSES (Hours)	SUPERVISED LABORATORY EXPERIENCE (Hours) D	
* RADIATION PHYSICS AND INSTRUMENTATION	Basic training in accordance USNRC Policy and Guidance Dective PC, 85-1, "Licensing Lixiscope and Bone Mineral	oir- g the 3 hours		
b. RADIATION PROTECTION	Analyser" presented by Will J. Walker, Jr., Ph.D., a ph certified by the American E of Health Physics.	ysicist 2 by		
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Included in "a" above			
H RADIATION BIOLOGY	Same as above	3 hours		
-	William J. Walker, Ph.D.,	СНР		
5. EXPERIENCE WITH R	ADIATION. (Actual use of Radioisotope	es or Equivalent Experien	cel	
ISOTOPE   MAXIMUM AMOUNT   WHER	E EXPERIENCE WAS GAINED DURATE	ON OF EXPERIENCE	TYPE OF USE	
	ADIATION. (Actual use of Radioisotope	es or Equivalent Experien		

RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER: The Radiation Safety Officer is responsible for assuring continued compliance with regulations and license conditions on a day to day basis. The responsibilities of the RSO include the following: Thorough familiarity with the radiation protection a. regulations and license conditions pertinant to the licensed facility. Initial and periodic (at least annual) documented b. reviews of radiation safety instructions, including regulations and license conditions, to all radiation workers at the facility. This includes security or housekeeping if they have keys to the radiaiton storage area. Routine review of any radiation exposure records, such C. as radiation survey results of incoming sources, or personnel dosimetry reports (if required), and maintain records. d. Routine review of safe handling procedures for radioactive materials and shipments, as well as security procedures to prevent any unauthorized use, loss or theft. Maintain accountability records of all incoming or e. outgoing radioactive material shipments or tranfers. f. Assure proper completion and records of Department of Transportation (DOT) shipping papers and labeling of outgoing shipments or transfers. Prepare amendment applications for any changes in the g. licensed operations. Such as changes in: (1) Facility address or storage room (2) RSO or users (3) Maximum possession limit (4) Radioactive isotopes (5) Eandling, operating procedures or records Schedule and maintain any license/regulatory requirements such as, the scheduling and maintenance of required records. Item 7 11/12/84

- i. Maintain all records required by regulations or license conditions for inspection.
  - j. Be available during regulatory agency inspections.
  - k. Review and maintain copies of regulatory agency correspondence and notices.
  - 1. Report any loss or theft of radioactive materials to the licensing/regulatory agency. Obtain consultation if there is doubt on whether or not a specific incident is reportable.
  - m. Assure proper posting of required "Notice to Employee" signs; "Instructions to Workers" notices; Caution Radioactive Material" labels where appropriate.
  - n. To remove radiation labels on any empty containers that are to be discarded.

TRAINING AND EXPERIENCE

ITEM 8

# Bone Densitometry Radioisotopes Licensing Course

### COURSE OUTLINE

### DAY 1 Physics, Biology and Protection

### I. BASIC RADIATION PHYSICS

- A. The Atom
- B. Nuclear Families
- C. Categories of Atomic and Nuclear Radiations
- D. Characteristics of Ionizing Radiation
- E. Modes of Radioactive Decay
- F. Mathematics of Radioactive Decay
- G. Radioactive Decay Schemes
- H. Man-Made Radiations
- I. Balf-Value Layer
- J. Inverse Square Law
- K. Half-Life
- L. Radiation Units
- M. Sealed Sources

#### II. RADIATION BIOLOGY - PHYSICO-CHEMICAL RADIATION

- A. Types and Sources of Ionizing Radiation
- B. Excitation and Tonization
- C. Interactions of Radiation with Matter
- D. Comparisons of Ionizing Radiations
- E. Chemical Effects of Radiation
- F. Radiolysis of Water
- G. Effects of Radiation on Biologically Important Molecules
- H. Damage to DNA
- I. Consequences of Damage to DNA
- J. Radiation Damage to Other Cell Molecules
- K. Modifiers of Molecular Sensitivity
- L. The Physico-Chemical Lesion

#### III. RADIATION BIOLOGY - EFFECTS

- A. Low Dose Effects
- B. Genetic Effects
- C. Radiation Induced Mutations
- D. Somatic Cell Mutations
- E. Germ Cell Mutations
- F. Implications of Genetic Effects in Bumans
- G. Radiation Carcinogenesis
- H. Radiation Induced Cancers
- I. In-Utero Effects of Radiation
- J. Evaluation of Radiation Exposure in Pregnancy
- K. Risks and Benefits of Medical Uses of Radiation
- L. Radiation Doses to Tissues

#### IV. RADIATION SAFETY

- A. The "ALARA" Philosophy
- B. Basis For Maximum Permissible dose
- C. Time, Distance and Shielding
- D. Characteristics of I-125
- E. Instrumentation
- F. Leak Testing and Contamination Control

#### V. RULES AND REGULATIONS

- A. "Standards for Radiation Protection" 10 CFR Part 20 and "Instructions to Radiation Workers" 10 CFR Part 19, and Equivalent Agreement State Regulations
- B. License Conditions for Radiation Safety Program
- C. Radiation Labels and Required Posting and Documents
- D. Radioactive Shipment Receiving, Opening, Bandling, Storage and Security Procedures
- E. Routine Proper Use, Inventory and Accountability Procedures for Sealed Sources
- F. Shipment Returns, DOT Regulations and Supplier Instructions and Forms
- G. NRC Draft Regulatory Guide "Instructions Concerning Prenatal Radiation Exposure" Dated November 1975
- H. Title 10 CFR Part 35 "Medical Use of Radionuclides" and NRC Regulatory Guide 10.8 Procedures and License Applications
- I. Radiation Safety References, NCRP and ICRP Publications

VI. EXAM

### DAY 2 Clinical Applications

- I. Principles of Photon Absorptiometry
- II. Photon Absorptiometry In The Clinical Facility
  - A. Areas of Clinical interest
  - B. Initial evaluation
  - C. Serial evaluation
- III. Guidelines of Quality Scanning
  - A. Precision and Accuracy
  - B. Tests of quality
    - 1. Profile
    - 2. Bone width
    - 3. Source strength
  - IV. Clinical Use of Photon Absorptiometry -
    - A. Densitometry Demonstration and Scanning to review positioning and measurement methodologies.
    - B. Scanning Procedure exercise for all participants to qualify for license

INSTRUMENTATION:

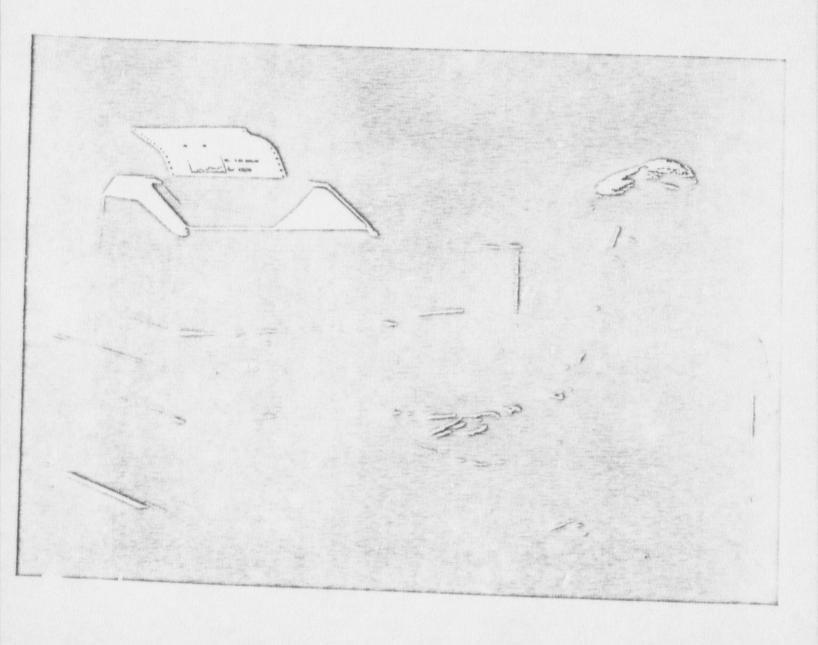
Radiation Survey Meter:

Radiation Victoreen Model 493, Beta/Gamma, X-ray GM Survey Meter or equal. End-window 1.4 mg/cm-sq, Ø to 50 mR/hr.

Bone Densitometer:

Norland Digital Bone Densitometer model 278A (N2740 and N2780), product information attached.

BONE DENSITOMETER
RODEL 278A ... A CRITICAL ADVANCE
IN BONE QUANTIFICATION



## /JILLIC/TIONS

CLINICAL INVESTIGATORS CALLED THE MODEL 278 DENSITOMETER "A PROMISING TOOL." NOW THE MODEL 278A CAN MEASURE A PENCIL-LEAD SIZED EONE WITH AS LITTLE AS 0.05 g/cm EONE MINERAL CONTENT. IT'S MORE PROMISING THAN EVER—AND MORE USEFUL:

- to any medical specialty concerned with bone disease or disorder . . . for diagnosis of skeletal demineralization as in advanced osteoporosis . . . and for data on response to therapy. 14-18
- to pediatricians and neonatalogists for use in small infants... to measure delayed bone mineralization... and to investigate therapeutic measures that might correct osteopenia of prematurity.\* (Figure 1)

- to nephrologists for the monitoring of renal osteodystrophy . . . calcification after transplant . . . and the adjustment of dialysis treatment.
- to researchers for rapid and accurate, in vivo, non-intrusive determinations measuring bone mineral in the laboratory rat, dog or rabbit.
   (Figure 2)
- to race horse owners, trainers and veterinarians for assistance in determining when a horse is mature enough to start running.<sup>12-13</sup>
- e and . . . to aid clinical investigators in population surveys¹6, for the study of inheritance patterns¹7, nutritional research¹6, exercise programs¹6, and pharmaceutical testing programs.20



## LONE OUVINILLEVIOUS

A KLED - A SOLUTION

Finysicians and clinicians have long recognized the shortcomings of biopsy or radiograph methods for the early detection of bone disease. In 1963, necessity once again gave birth to invention. Cameron and Sorenson reported a

new In vivo, non-intrusive technique for quantifying bone mineral content—the photon absorption technique. Since then, the technique has grown in sophistication and gained widespread clinical approval.<sup>2,3</sup>

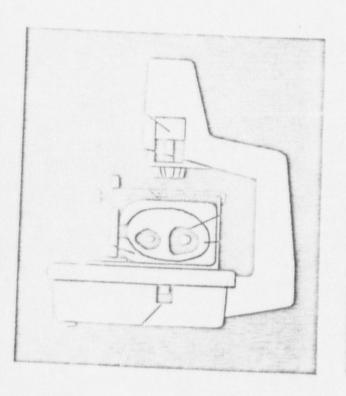
THE PHOTON ABSORPTION TECHNIQUE
This technique replaces the broad energy
spectrum of the x-ray beam with a beam of
monoenergetic photons. This beam passes
through the soft tissue and bone of a limb, and
the resulting attenuation is monitored with a
photon detector. The mass of bone mineral

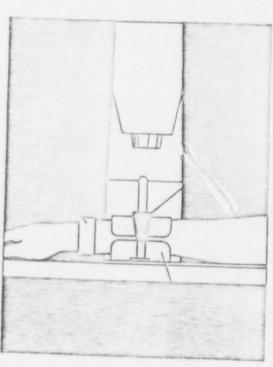
present may be derived from the number of photons absorbed by the bone. Using a highly collimated beam from a monochromatic photon source, this measurement technique offers great advances in sensitivity, safety, accuracy, precision, and practical usefulness.

THE 278A DIGITAL BONE DENSITOMETER

This proven instrument makes the advantages of the photon absorption technique available to you in a simple 5 minute procedure. Without causing patient discomfort, the densitometer measures bone mineral content as a linear density in grams per centimeter and bone width in centimeters. When measuring an adult radius, you can expect precision of ± 0.006 g/cm—and even better for

smaller bones. Compare this sensitivity to that of the radiograph, which is unable to detect anything prior to a 30-40% change in bone mass. In addition, the expanded capacity of the 278A Densitometer allows it to detect bone mineral content as low as 0.05 g/cm.







## SCANNER AND COMPUTER MODULE

### HOWATHE SYSTEM WORKS

The 278A provides step by step instructions for easy and effective operation. Once the patient is positioned, the scanner module transports a collimated photon beam from a radioactive source (lodine-125) across the chosen scan site. A search scan locates the bone of interest within the limb. Then a measurement scan collects more accurate photon absorption data. The results are computed and displayed digitally on the CRT screen.

### SCAN SITE SELECTION

The densitometer primarily measures the bones of the forearm, but can be adapted to measure a variety of other scan sites. Norland has recommended the forearm as the primary site because bone mineral content of the mid-distal radius has been shown to reflect with reasonable accuracy the mineralization of the entire axial skeleton. The radius is also an easy bone to measure. The scanner's positioning system holds the forearm firmly but comfortably and minimizes repositioning errors.

With an accessory positioning system the densitometer can measure fingerbones, 7.0 a site often monitored in renal osteodystrophy. It can measure the ulna, tibia, fibula, and the humerus in newborn infants. 9 It can also be adapted for use with animals, ranging from the femur of the laboratory ratio to the tibia of the beagle! 1 to the metacarpal of the horse. 12,13

# SYSTEM CAPABILITIES AND OPTIONAL COMPONENTS

THE 278A DENSITOMETER WASTES NO TIME—FOR PATIENT OR OPERATOR

- After power turn-on, the computer performs a rapid and extensive self-check; any malfunctions are indicated on the screen.
- Calibration is a simple five minute procedure which need be done only once every two weeks.
- Multiple scans are now possible with the 278A, and are performed without stopping for operator key press.

### COMPLETE CRT DISPLAY

All information about a scan is presented on a large, bright CRT display:

- onumeric results: BMC (bone mineral content), BW (bone width), and BMC/BW
- graphic results: bone profile showing selected baseline and bone edges
- scan number: 9-digit patient I.D., date, sequence number, and disk file number
- scan parameters: which bone, edge threshold, collimator, etc.

### OPTIONAL COMPONENTS

Compact High Resolution Printer/Plotter

Provides four different modes of printed record ranging in complexity from:

Printing out the scan number with BMC, BW, and BMC/BW in about three seconds

to printing all information shown on the CRT screen, including a plot of the bone profile, in about one minute.

All printouts done at a press of a button. Connects to the computer module with a single cable.

### Flexible Disks, Permanent Storage Memory

Single or dual drive units with five diskettes included. Bone measurement information is written on a diskette for permanent storage. Data may be retrieved and displayed on the CRT for examination and/or computation. Connects to the computer module with a single cable. A valuable aid in serial patient measurement.

### Scanning Positioning System

Adapts the scanner for measuring the arm bones, finger bones, infant subjects, and animals. Specific positioning systems allow accurate repositioning of the scan site.

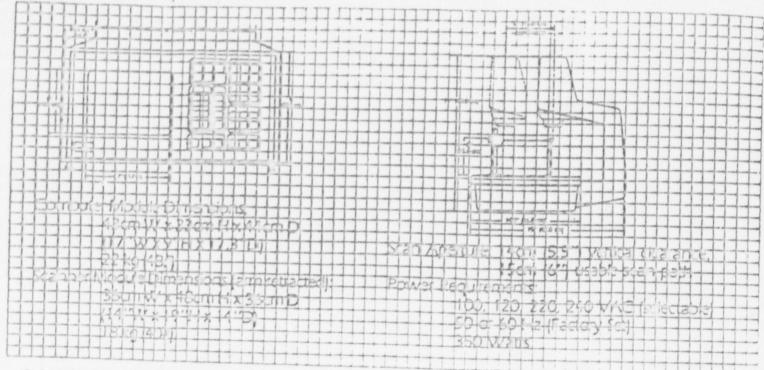
For more information contact 1-800-558-0158

NORLAND [

Industrial Scientific and Modulal Instrumentation Boute 4. Notwood Drive. For Allorson, WA 53538

1-4-14-563-6456 TLX 26-5448 1-600-558-0158 (Talf-Free) Affiliate of Condic Comp. Mariel 216/4

### THIS STALL SPECIFICATIONS



### A NOTE ON RADIATION DOSAGE

Comparing the densitometer with radiography for radiation dosage is conceptually difficult. A radiograph exposes a large portion of the body. while the densitometer exposes a section of tissue measuring approximately five mm wide and three cm long. A rough comparison can be

#### REFERENCES

- 1. Cameron J.E. Scrercon J.: Missourement of bone mineral hydro. An proposed method Spence 142, 230-232, 1963.
- Coren, S.H., Aloiz, J.F., Letter, J.M. Noninvasive measurements of bone mass and the direct syntiance Cold Team Pg 26, 1-3, 1978.
- 3. Cohn, S.H., Normassia Magazerrens of Bane Mass and Their Cleane Arthornians, CEC Fress, West Patri Boach, FL, 1900.
- 4. Need, E.H. Ferformerick the extensions of the Norward model 2784 bone of the interior, Norward Applications Note: For Attension, WI, 1982.
- JOHNSON C.C. Smot D.M. YU. P.L. Dess. W.P. In vivo measurement of bone mass in the reduce Metaholom 17, 1140-1153, 1968
- 6. Martin, R.B.: Estimation of bone and steleral weight by direct photon orp onery these forta 6 52-60, 1971.
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## CORPORATION



industrial Scientific and Medical Instrumentation. Route 4, Norland Drive, Fort Attention, WI 53538

1414-563-9456 TLX 26-5448 1-600-558-0158 (Tof-Free) Affiliate of Cords Corp.

. CALIFFATION OF INSTRUMENTS Calibration of Survey Instruments: Survey instruments will be calibrated at least annually A. and following repair. Procedures and sources have been approved by the State of Maryland, License MD-31-035 01 and U.S.NRC B. Regulatory Guide 10.8. Survey instruments will be callbrated by a consultant C. or outside firm. Name: Health Physics Services, Inc. Location: 4 Research Place, Suite 140, Rockville, MD 20850 SURVEY INSTRUMENT CALIBRATION PROCEDURES Source Sealed Cesium-137 source of approximately 500 mCi, authorized under Maryland License No. MD-31-035-01, for calibration purposes. The exposure date at discrete distances has been determined with NBS traceable ion chambers by a certified radiological physicist. These measurements are re-certified annually. Procedures 1. Turn on instrument to be calibrated and check batteries, etc. Replace as necessary. 2. Prepare calibration certificate in duplicate. 3. Unlock calibrator and remove source plug. Compare instrument at two points on each scale (approximately 30% and 70% of scale), to known exposure level. If deviation from true exposure exceeds +10%, make appropriate adjustments in accordance with the instrument manual. After appropriate adjustments, repeat Item 4 above. If deviations still exceed +10%, forward for appropriate maintenance with customer's consent. 6. Complete calibration certificate and insure that true exposure and meter response is listed for two or more points on each scale. 7. Replace plug, lock calibrator, and sign certificate. Item 10 11/12/84

- 8. Insure that certificate accompanies instrument when returned to customer.
- 9. Affix calibration sticker, with date of calibration, on side of meter and pack for shipping.

NOTE: Instruments used to measure low energy range isotopes, e.g., I-125, Tc-99m, Xe-133 shall also be calibrated with a Co-57 source of approximately 10 mCi (ICN Model 77321 or equivalent) for relative response comparison.

### FACILITIES AND EQUIPMENT

- A. A diagram of the facility where the Bone Densitometer will be used is attached.
- B. Security
  - 1. Storage:

All sources, when not secured in the scanner, will be stored in a locked steel storage cabinet. The source in use is locked in the scanner. Keys will be controlled by the Radiation Safety officer.

2. Handling Area:

The door to the where sources are stored and used is secured and area locked when not occupied by or under the direct observation of the RSO or an individual designated by the RSO as responsible for source security. These same individuals will have possession of the keys to this area.

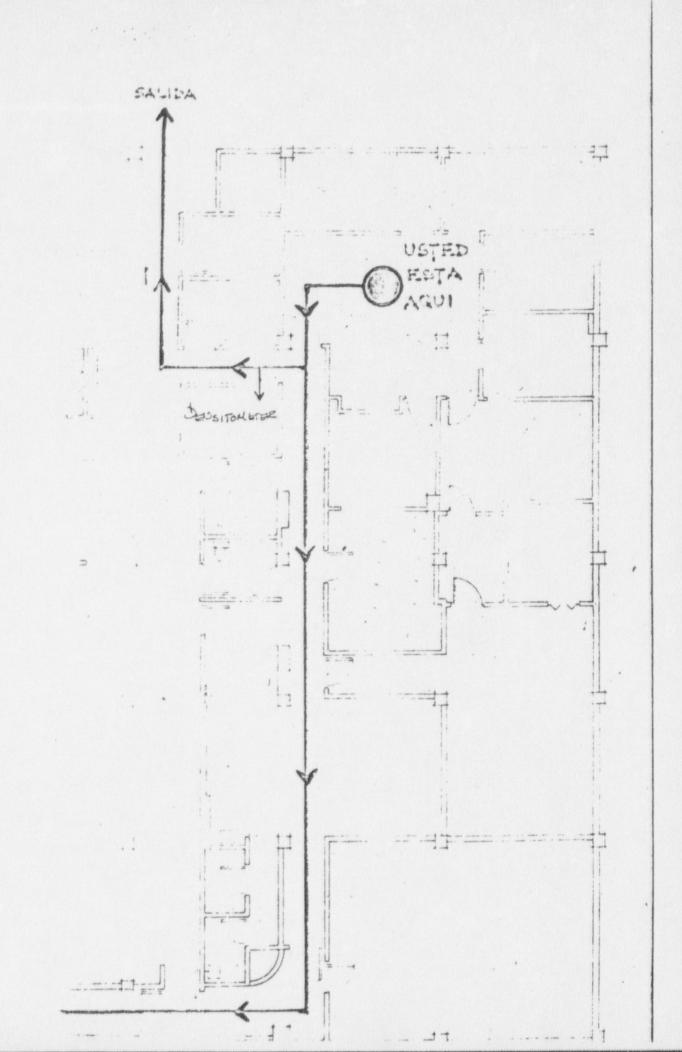
3. Building:

The building has an operational security system for non-working hours.

4. Remote Handling:

All sources will be received and shipped in shielded brass capsules (AECL Model C-236 source holders) to and from the supplier so no remote handling equipment will be required. However, a pair of long handled tongs will be available for emergency operations involving surface contamination of the brass capsule.

The manfacturers instructions will be followed when replacing sources.



All personnel whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) will be informed about radiation hazards and appropriate precautions.

Personnel will be properly instructed:

A. Before assuming duties with, or in the vicinity of, radioactive materials.

B. During annual refresher training.

C. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction will include:

A. All terms of the license pertinent to radiation safety.

B. Areas where radioactive material is used costored.

- C. Potential hazards associated with radioactive material.
- D. Radiologial safety procedures appropriate to their respective duties.
- E. Pertinent NRC regulations.
- F. Rules and regulations of the license.
- G. Obligation to report unsafe conditions to the radiation safety officer.
- H. Apropriate response to emergencies or unsafe conditions.
- Right to be informed of their radiation exposure and bioassay results.
- J. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence).

### ORDERING AND PROBLETING RADIOACTIVE MATERIALS:

- A. Sources will be ordered only at the direction of the Radiation Safety Officer.
- B. Sources will only be received during normal working hours and only by the Radiation Safety Officer or individuals specifically designated by the Radiation Safety Officer.
- C. Packages containing sources will be received and opened in accordance with the following procedures (item 14) and proper records maintained.

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL A. Packages 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. The appropriate regulatory office will be notified, in accordance with applicable regulations, if removeable contamination exceeds 0.01 uCi/100 cm sq or if external radiation levels exceed 200 mR/hr at the package surface of 10 mR/hr at 3 feet (or 1 m). The following additional procedures for opening packages will be carried out: Put on gloves to prevent hand contamination. Visually inspect package for any signs of damage (e.g. 2. wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If > 10mR/hr, stop procedure and 3. notify Radiation Safety Officer. 4. Measure surface exposure rate and record. If >200mR/hr, stop procedure and notify Radiation Safety Officer. Open the package with the following precautionary 5. steps: Open the outer package (following manufacturer's a. directions, if supplied) and remove packing slip. b. Open inner package and verify that contents agree with those on packing slip. Compare requisition, packing slip, and label on source holder. Check integrity of final source container. C. d. Check also that shipment does not exceed possession limits. 6. Wipe external surface of final source container and remove wipe to low background area. Check wipes with a thin-end window G-M survey meter, and take precautions against the spread of contamination as necessary. Monitor the packing material and packages for contamination before discarding. Item 14 11/12/84

a. If contaminated, treat as radioactive waste.

- b. If not contaminated, obliterate radiation labels before discarding in regular trash.
- c. Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Pecord". (attached)

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL A. Wear disposable gloves at all times while handling radioactive materials. Monitor hands and clothing for contamination after each procedure when sources are handled out of the Bone Densitometer. C. Wear personnel monitoring devices (films badge or TLD) at all times while in areas where radioactive materials are used or stored. Film badges if worn, should be worn at chest or waist level and TLD ring badge on dominant hand. Personnel monitoring devices should be stored in the designated low background area when not in use. D. TLD finger badges will be worn during all source handling procedures. Never remove sources from brass shielding capsules. E. F. All radioisotopes will be stored in a locked steel cabinet designated specifically for that purpose. Keys will be controlled by the Radiation Safety Officer. Appropriate records of serial numbers, dates, leak tests, and shipments of sources will be kept as required in the regulations. Disposal of old sources will be accomplished only by shipping the sources to the supplier, who has agreed to dispose of such sources. Sources are leak tested by Beta Diagnostics prior to shipment to the Diagnostic Centers. Sources will be shipped back to Beta Diagnostics before the six month deadline for mandatory leak testing elapses. J. Extremities of no one, except the patient, shall be placed in the primary beam. Sources will only be exchanged by the Radiation Safety Officer or other persons designated by the Radiation Safety Officer who have had specific training by Norland/Beta Diagnostics personnel to safely exchange sources. During source exchange, the open port of the source should always be directed away from other persons or occupied areas. In exchange, the port should be directed toward the windows in the scanning room. Item 15 11/12/84

#### EMERGENCY PROCEDURES

- A. In the event of a radiation incident involving the rupture of an I-125 source container, the Radiation Safety Officer or persons under his/her supervision will isolate the source by removing all persons in the immediate area and cover the source with radiation absorbing material. Removal and disposal will be coordinated by Beta Diagnostics, Inc. assisted as necessary by a qualified expert in the field of health physics (Health Physics Services, Inc.)
- B. In the event of a radiation incident involving non-closure of a scanner shutter assembly, the Radiation Safety Officer or persons under his/her supervision will isolate the source by removing all persons in the immediate area and place over the scan path a radiation absorbing material. Appropriate action will be taken after careful consideration.
- C. All incidents will be reported immediately to the RSO.

Radiation Safety	Officer: LAURA LESPIEK-DEXIEK, N	
Office Phone:	(809) 787-9353	
Home Phone:	789-7856	
Alternate(s)		
Name:		
Office Phone:		
Home Phone:		

- A. All source usage and storage areas will be surveyed monthly with an appropriate low-range survey meter. The surveys will consist of a measurement of radiation levels with a survey meter sufficiently sensitive to detect C.1 mR/hr.
- B. 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.
  - 2. Name of person conducting survey.
  - 3. Drawing of area surveyed, identifing relevant features such as active storage areas, etc.
  - 4. Measured exposure rates, if any above background, keyed to location on the drawing (point out rates that require corrective action).
  - 5. Corrective action taken in the case of excessive exposure rates, exposure rates after corrective action and any appropriate comments.

WAST'E MANAGEMENT

Clinics will return used sources in their brass shields, packaged in accordance with DOT and NRC regulations, to Beta Diagnostics, Inc., Fort Atkinson, WI for disposal. Beta will hold sources until a sufficient quantity has accumulated for shipment back to the manufacturer. This will be done in accordance with all State, NRC, and DOT regulations.

DIAGNOSTICS, INCORPORATED

BETA DIAGNOSTICS, INC.

I-125 RADIOISOTOPE

RETURN POLICY

DEC. 1, 1934

Due to the ever increasing costs of materials and new safety standards we request that you return your old I-125 rediocative source as soon as you have received your new source.

Your new source is priced with the essumption that your old source will be returned to Bata Diagnostics within 30 days of the date your new source is shipped to you. This allows one week for shipping in each direction plus two weeks for you to change the source.

To simplify the return of your old source we have included all of the hazardous materials labels required by the U.S. Dept. of Transportation and United Parcel Service. Please follow the instructions enclosed with your new source. If you have any problems with local UPS pick-up call Jody Schemm of Beta Diagnostics at 414/563-9341 for assistance.

Should your old I-125 source not be retruned within the 30 day period you will be receiving an extra invoice for \$50.00 to cover the value of the brass shielding and shipping capsule which we have not been able to recycle.

Please recall that if you maintain any one source in your possession for more than six months you must conduct a leak test and have data on record to prove the results were negative. To eliminate the need for your leak testing and to provide the maximum safe guards please return your source promptly and leave the leak testing to Beta Diagnostics. The recycled source capsule will also keep your costs down. If you follow our recommended five month new source cycle time you will be able to avoid all need for any leak tests except in the event of any accidental damage to the source or shipping container.

Thank you for your I-125 source order. Please call us if you have any questions or problems with your I-125 source.

Jody L. Schemm Isotope Distribution Mgr.

210 Madison Avenue, Fort Atkinson, WI 53538 (414) 563-9341
7540 Louis Pasteur Drive, Suite 100, San Antonio, TX 78229 (512) 690-1548

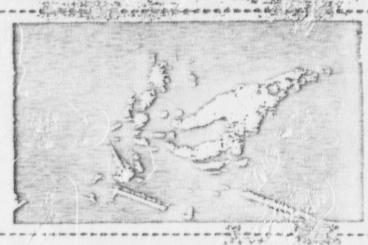
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THE THE THE THE

A. Lift source/shutter door.



B. Remove source cap. Hold source in position shown.



C. Screw source into source/shutter door, then close door.

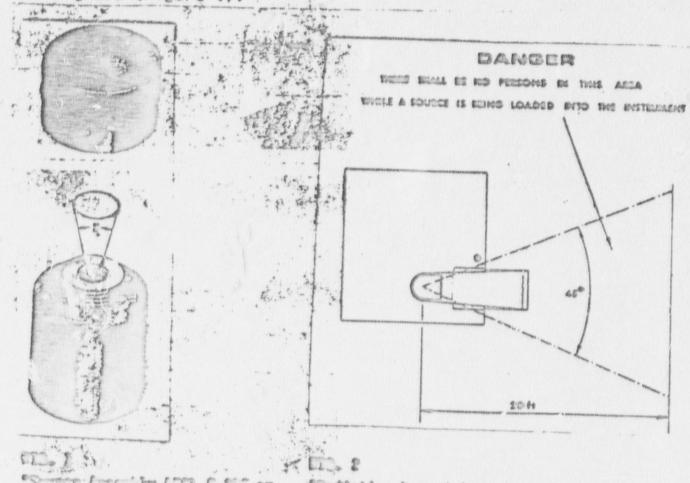


D. Store cap for later use on clip in scanner.



all their templated to be harmed think to Re

The rediction source is contained in a source holder which absorbs almost all of the emitted rediction when the cover is in piece. Use caution when removing the source holder cover. When the cover is removed (by unscrewing), the radiction beam emerges from the small hole with a total angular spread of approximately 30 degrees (Figure 1).



"Scarce Assembly ACCE C-250 cr 178/251A with shipping cap recoved 30 degree rediction field filustrated."

- Rediction forerd area during source Tooding

A 200 mC1 source delivers a maximum dose rate of approximately 200 mr/min at a distance of 2.5 cm. The protective cover should not be removed until the source is actually installed in the scanner. When installing the source, be sure that there are no partons in the scanner area indicated by Figure 2.

Turn off the Densitometer before starting the source installation. Remove the thumb screws holding the deck to the scanner base (two in front and one in beck). Disconnect the cable from the back of the scanner. Unlock the deck from the base by turning the deck key counter-clockwise several turns until the desk is free.

While loading or unloading the source, keep fingers away from the exposed end of the source holder at all times. Do not point the exposed source toward anyone. When removing the source from the scanner, reverse the loading procedure. Be sure to replace the cap on the source holder before transporting the source.

### BIO-MEDICAL APPLICATIONS OF BAYAMON, INC.

A Division of National Medical Care, Inc. Call Box 60 I.R. Carr. #2 Km. 11.2 Bayamón, Puerto Rico 00621 Tel. (809) 787-9353

#### FOREWORD

Tonizing radiation is among the most versatile and useful tools of modern medicine and biomedical research. Like many other instrumentalities of medicine, ionizing radiation is potentially hazardous unless used with strict adherence to safety rules and procedures. Thus, the safety rules which govern the uses of radiation are concerned with preventing genetic damage as well as with protecting the health of the exposed individual.

The rules and procedures set forth here have one single, straightforward purpose: to protect the patients, employees, and visitors from unnecessary and potentially harmful radiation.

The existing radiation safety program has many facets designed to keep the levels of exposure to personnel at a minimum. This program has three main phases:

### PHASE 1

Achieve the objective of maintaining radiation exposures to "As Low As Reasonably Achievable" (ALARA) to employees, visitors.

### PHASE 11

Control operational procedures by the user of radiation sources.

### PHASE 111

Evaluate the radiation safety program performed by the Radiation Safety Officer and the health physics consultant.

We, the management, are committed to the program procedures and develop new procedures as appropriate to implement the ALARA concept.

Administrador

Date 27 1986

### BONE DENSITOMETER CLINIC

### RADIATION SAFETY PROGRAM (ALARA)

#### I. MANAGEMENT COMMITMENT

- A. The management of this facility is committed to the program described herein for keeping radiation exposures to as low as reasonably achievable.
- B. We will perform a formal annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.
- C. Modification to procedures will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

### II. RADIATION SAFETY OFFICER IS RESPONSIBLE FOR THE FOLLOWING:

- A. Annual and Quarterly Review
  - Annual review of the Radiation Safety Program. The RSO will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts.
  - 2. Quarterly review of Occupational Exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph III of this program.
- B. Education Responsibilities for an ALARA Program
  - The RSO will assure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in ALARA philosophy and informed that management, is committed to implementing the ALARA concept.
- C. Cooperative Efforts for Development of ALARA Procedures

  Radiation workers will be given opportunities to participate in the formulation of the procedures that they will be required to follow.

Reviewing Instances of Deviation from Good ALARA Practices D. The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA. III. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION EXPOSURES

This facility hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Sarety Officer or his consultant. The Investigational Levels that we have adopted are listed in Table 1 below. These levels are to the exposure of individual workers.

#### TABLE 1

Investigational Levels -(mrems per calendar quarter)

	LEYEL_I	10 X 5 14 _ 4 4
1. Whole body	125	375
2. Hands	1875	5625

The Radiation Safety Officer will review the results of personnel monitoring, film badge report, not less than once in any calendar quarter, as is required by 10 CFR 20, 20.401. The following actions will be taken at the Investigational Levels as stated in Table 1:

Quarterly exposure of individuals to less than A. Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table 1 values for the Investigational Level I.

Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required.

C. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, take action. The investigation will be documented and made available to NRC inspectors for review at the time of the next inspection.

### IV. SIGNATURE OF CERTIFYING OFFICIAL

I hereby certify that this institution has implemented the ALARA Program set forth above.

Signature of Radiation Safety Officer

LAURA LESPIER-PEXTER, M.D.

Name (type or print)

PHYSICIANS

Title