NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION **APPLICATION FOR MATERIALS LICENSE – MEDICAL**	Approved by OMB 3150-0041 Expires 9-30-83

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**

Orthopedic Associates of Virginia, Inc.
6275 Virginia Beach Blvd.
Norfolk, Virginia 23502

TELEPHONE NO.: AREA CODE (804) 461 - 1688

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

Suite #304
Medical Tower
Norfolk, Va. 23507

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Robert S. Neff, M.D.

TELEPHONE NO.: AREA CODE (804) 461 1688

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

a. [X] NEW LICENSE
b. [ ] AMENDMENT TO LICENSE NO. _____
c. [ ] RENEWAL OF LICENSE NO. _____

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Robert S. Neff, M.D.
Joel Andrew Mason, M.D.

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.)*

Robert S. Neff, M.D.

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
Iodine-125	Sealed Source See NRC Registr. Sheet NR-430-D-102-S Source Model # AECL C 324	2 Sources/ No source to exceed 400 mCi.	Lunar Corp. FP^2 Rectilinear Forearm Scanner
Gadolinium-153	Sealed source See NRC Reg. Sheet NR-430-D-101-S Gulf Nuclear # GD-1	2 Sources/ No source to exceed 1,500 mCi.	Lunar Corp. DP$_3$-AT-SP2 Dual Photon Scanner

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License Fee Information on cover ltr

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. 1 Date: 10-80

7. MEDICAL ISOTOPES COMMITTEE	
	Names and Specialties Attached; and
	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE Refer to Enclosure for Item 8.	
	Supplements A & B Attached for Each Individual User; and
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
	Appendix C Form Attached; or
X	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
X	Equivalent Procedures Attached; and
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
	Appendix F Procedures Followed; or
X	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
	Appendix G Rules Followed; or
X	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
	Appendix H Procedures Followed; or
X	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
	Appendix I Procedures Followed; or
X	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
	Appendix J Form Attached; or
X	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM		
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R. S. Landauer, Jr. & Co., Glenwood, Il	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

Refer to attached ALARA Program

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

N/A

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

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

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)*

(1) LICENSE FEE CATEGORY:

(2) LICENSE FEE ENCLOSED: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* Robert S Neff MD

(1) NAME *(Type or Print)* Robert S. NEFF

(2) TITLE

c. DATE March 24, 1986

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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 (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 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 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.

5. **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.

Element and Mass #	Chemical&/or Physical form	Max number of millicuries each form	Describe Purpose of Use
I-125	sealed source	2 sources/ no source to exceed 400 mCi.	Norland Bone Densitometer (N-2740 with N2780 Module)

Source model #AECL C-235&C234 and Source Holder Model C-236

See NRC Registr. Sheet NR 482-D-102-F Aug. 1983

Gadolinium-153	sealed source	2 sources/ No source to exceed 1,500 mCi.	Norland 2600 Dichromatic Bone Densitometer

Source Model: Norland Gadolinium Series

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:

a. Thorough familiarity with the radiation protection regulations and license conditions pertinant to the licensed facility.

b. Initial and periodic (at least annual) documented 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.

c. Routine review of any radiation exposure records, such 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.

e. Maintain accountability records of all incoming or 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.

g. Prepare amendment applications for any changes in the licensed operations. Such as changes in:

   (1) Facility address or storage room

   (2) RSO or users

   (3) Maximum possession limit

   (4) Radioactive isotopes

   (5) Handling, operating procedures or records

h. Schedule and maintain any license/regulatory requirements such as, the scheduling and maintenance of required records.

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.

l. 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

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Robert S. Neff, M.D.	Virginia

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

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	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Basic training in accordance with USNRC Policy and Guidance Directive FC, 85-1, "Licensing the ~~Lixiscope and Bone Mineral~~ Analyser" presented by William J. Walker, Jr., Ph.D., a physicist certified by the American Board of Health Physics.	3 hours	
b. RADIATION PROTECTION		2 hours	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Included in "a" above		
d. RADIATION BIOLOGY	Same as above	3 hours	
	JAN 17 + 18 1986 Copley PLAZA MARRIOTT Boston Mass		

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
		See attached Certificates of Achievement please		

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
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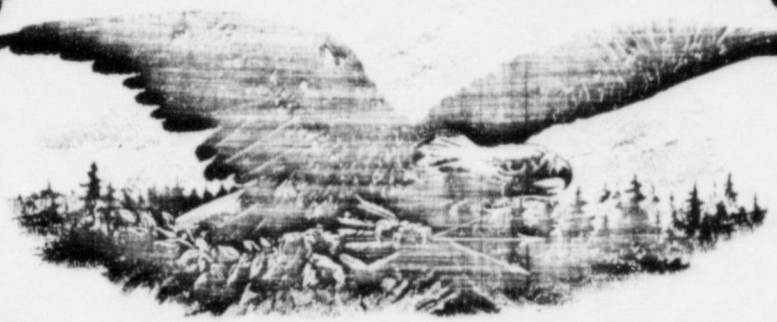
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Included in "a" above		
d. RADIATION BIOLOGY	Same as above	3 hours	
	JAN 17 + 18 1986 Copely PLAZA MARRIOTT BOSTON, MASS		

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
		see attached certificates of achievement please		



Certificate of Achievement

This Certificate is presented to

Joel Mason, M.D.

by Beta Diagnostics, Inc.

for Distinguished Achievement

Bone Densitometry Workshop

IN WITNESS WHEREOF, we have caused this Certificate to be signed

this 17th day of January in the year 1986

William Walker, Ph.D.
Signature

R. B. Wong, MD
Signature

Certificate of Achievement

This Certificate is presented to

Robert Neff, M.D.

by Beta Diagnostics, Inc.

for Distinguished Achievement

Bone Densitometry Workshop

IN WITNESS WHEREOF, we have caused this Certificate to be signed this 17th day of January in the year 1986

William J. Walker, Ph.D.
Signature

A. L. Billings, M.D.
Signature

INSTRUMENTATION:

Radiation Survey Meter:

Radiation Victoreen Model 493, Beta/Gamma, X-ray GM Survey Meter or equal. End-window 1.4 mg/cm-sq, 0 to 50 mR/hr.

Bone Densitometer:

Lunar Corporation- DP_3-AT/SP_2 Dual-Photon Spine/Femur with Single-Photon Attachment.

(This Combination System includes an IBM-AT Computer with 20 MB disk.)

******* OR *******

Norland Bone Densitometer N2740 with N2780 Module (single Photon)

Norland 2600 Dichromatic Bone Densitometer (Dual Photon)

The following pages include information on both the Lunar Single Photon and the Lunar Dual-Photon Scanners. I will, as indicated above, be using either the Combination System with the IBM-AT Computer, OR the Norland single and dual photon scanners. Information on the Norland equipment is also included.

Item 9
11/12/84

QUOTATION

Effective for 60 Days

CI 11662

LUNAR RADIATION CORPORATION
916 Williamson Street
Madison, Wisconsin 53703
(608) 258-8545

Date: March 4, 1986

Quote to: Dr. Joel Mason
6044 Newport Alscent
Norfolk, VA 23505

Item	Description		Cost
	Dual-photon spine/femur scanner including: dual channel nuclear counting electronics rectilinear scanner (28cm x 20cm) photomultiplier tube and divider software and operator manuals scan table/pad/positioning aides BMC standards training and installation IBM-PCA-AT Microcomputer and display with: 512K memory, 1.2 MB floppy disk 20 MB hard disk, 2 RS232 ports interface controller board		
	Epson FX85 Printer, Buffer and Cable		$39,50
	Single-Photon Scanning Attachment	$12,000	$12,00
	Gadolinium Source GD-153 Iodine Source I-125	$7500 $ 800	$8,30

TOTAL DUE $59,80

***** 10% DEPOSIT REQUIRED WITH ORDER *****

NOTES:

1. Gd-153 and I-125 sources are provided by a third party. I-125 must be returned or disposed of direcly to the supplier and not to LUNAR. Arrangements for the disposal of depleted Gd-153 sources can be made with the supplier or with LUNAR.
1. Warranty - one (1) year all parts and labor. Annual service contract can be obtained on the DPS-AT/SP2 for $4,120.
2. TERMS: Deposit to be applied as down payment when order is shipped; Net 30 days; interest at 1.5% after 30 days.
   WARNING: warranty voided if payment not received by 30 days.
3. Lunar Radiation does not accept any responsibility for use of this instrumentation other than that specified in the operators manual.
4. FOB Madison (freight prepaid and added to invoice).
5. Fees for local safety compliance are to be paid by purchaser.
6. Customs charges, if any, to be paid by purchaser.

Donna Biddle

Donna Biddle - Sales Administr

LUNAR RADIATION
CONFIGURATION — PRICE LIST

Model		
	Single-Photon Systems	
SP2	Rectilinear Single-Photon Scanner (Northstar Advantage Computer)	$19,90
SP2-XT	Rectilinear Single-Photon Scanner (IBM-XT Computer with 10 MB disk)	$23,25
SP2-AT	Rectilinear Single-Photon Scanner (IBM-AT Computer with 20 MB disk)	$25,25
	Dual-Photon Systems	
DP3	Dual-Photon Spine/Femur Scanner (Northstar Advantage Computer)	$32,15
DP3-XT	Dual-Photon Spine/Femur Scanner (IBM-XT Computer with 10 MB disk)	$37,50
DP3-AT	Dual-Photon Spine/Femur Scanner (IBM-AT Computer with 20 MB disk)	$39,50
DP4	Dual-Photon Total Body Scanner (DEC PDP 11/23 Computer)	$68,00
	Combination Systems (Single Computer with Single and Dual-Photon Scanners)	
DP3/SP2	Dual-Photon Spine/Femur Scanner with Single-Photon Attachment (Northstar Advantage Computer)	$44,15
DP3-XT/SP2	Dual-Photon Spine/Femur Scanner with Single-Photon Attachment (IBM-XT Computer with 10 MB disk)	$49,50
DP3-AT/SP2	Dual-Photon Spine/Femur with Single-Photon Attachment (IBM-AT Computer with 20 MB disk)	$51,50
	LUNAR Information Network Packages	
	300 Baud Information Network Package	$1,99
	1200 Baud Information Network Package	$2,29

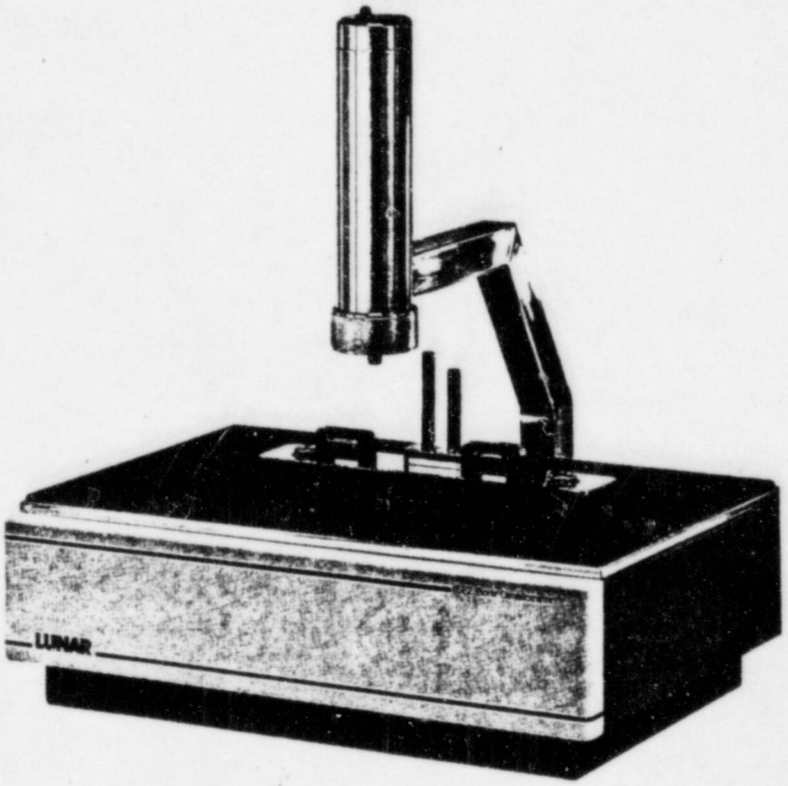
Terms

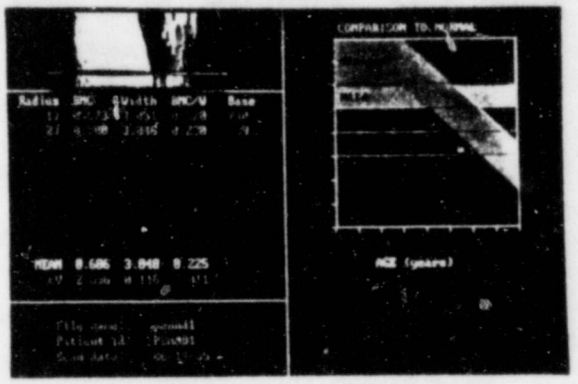
10% deposit required with order, Net 30 days
FOB Madison (Prepay and add freight)
Prices include 2 days installation/training
Warranty: 1 year
Service Contract: 8% of list price/year

NOTE:
PRICES DO NOT INCLUDE SOURCES

LUNAR SP2 BONE DENSITOMETER

From the World Leader in Bone Measurement





Available with IBM-XT and AT* computers for high-resolution color graphics, hard-disk storage.

APPLICATIONS

Renal disease.
Osteoporosis screening (>70 years).
Osteoporotic patients on therapy, as adjunct to dual-photon scans.
Premature infants' bone status.
Pediatric bone disease.

UNIQUE FEATURES

PRECISE.
Rectilinear scan with automatic measurement of bone width and interosseous space for precise repositioning (1-2%).

FLEXIBLE.
Measurement of any forearm site, including ULTRADISTAL (75% trabecular).
Selection of scan speed, step and number of scan lines.
Infant option – customized scanner platform for premature infants.

CLINICALLY RELEVANT.
Calibrated results compared to large database of normals for four sites. Adjusted for height, weight, age and ethnic group.

COST-EFFECTIVE.
Compatible with hundreds of IBM software packages.
Upgradable to LUNAR DP3 spine/ femur scanner.

EASY TO USE.
Automatic localization and menu-driven.

CONVENIENT.
No messy waterbath or leaky waterbag; uses encapsulated gel bolus.

LUNAR

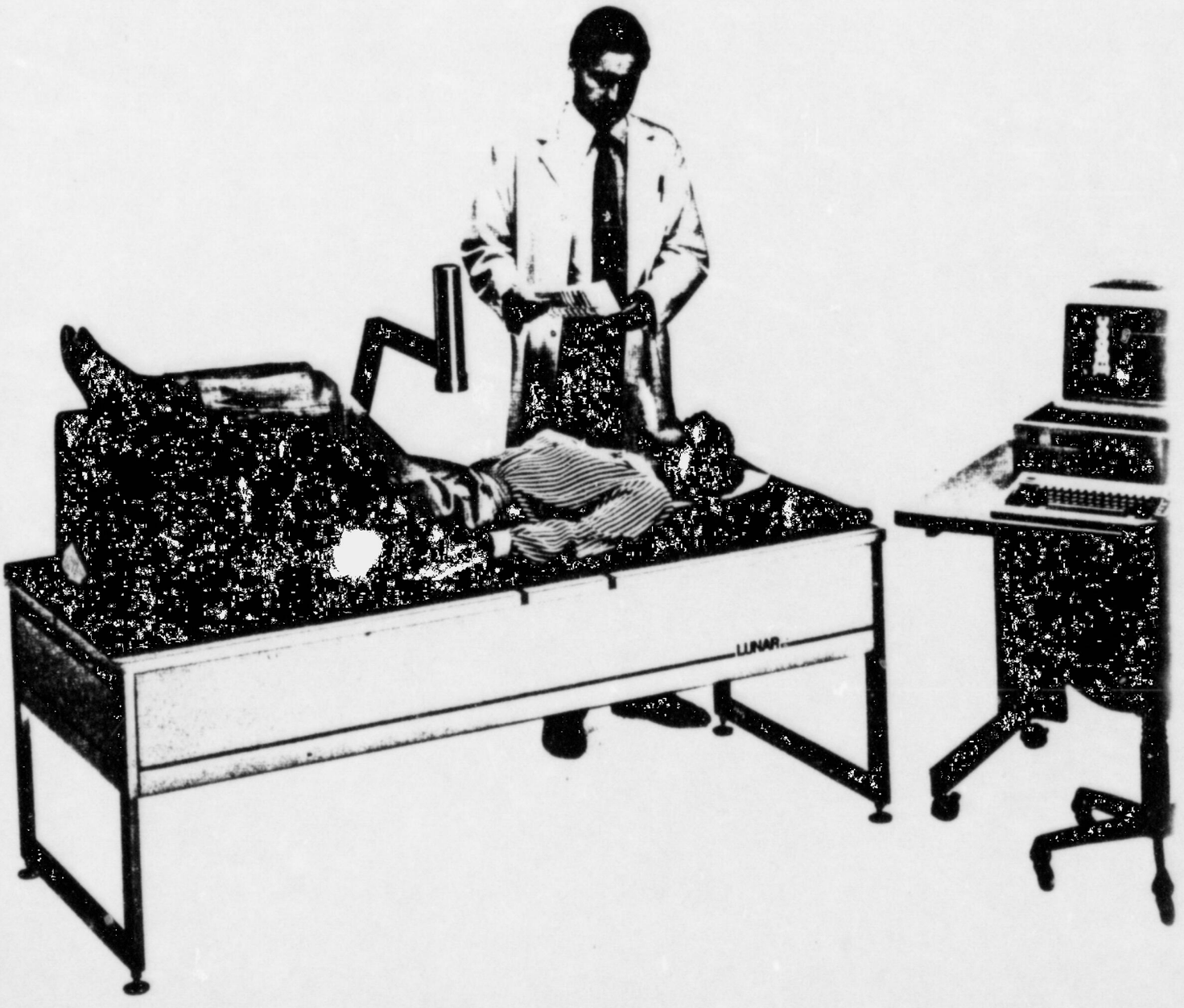
916 Williamson Street
Madison, WI 53703
(608) 258-8545

*IBM-XT and IBM-AT are trademarks of International Business Machine Corporation.

LUNAR DP3-XT/AT, The Unique Clinical Solution For Bone Densitometry

LUNAR

From The World Leader In Bone Measurement– DP3 Spine/Femur Scanner



LUNAR *Is* Absorptiometry

Dual-Photon Absorptiometry

Dual-photon absorptiometry utilizes an isotope with two energy levels (^{153}Gd), thereby eliminating the need for uniform soft-tissue cover over the bones of interest. Dual-photon absorptiometry has been selected by the American College of Physicians as the method of choice for measuring bone density because of its low radiation dose, low cost and high sensitivity. LUNAR's DP3-XT, and DP3-AT are the most advanced dual-photon systems.

Applications

The DP3 serves an important role in osteoporosis and other bone diseases. Various endocrine disorders, renal disease, and many medications lower bone density. DPA measurements are invaluable in assisting physician diagnosis and treatment of these diseases. The value in early detection of osteoporosis (prior to generalized skeletal loss) is well-recognized. Baseline readings on women prior to the menopause can give an early indication of those with low peak bone mass and/or early loss.

Equally valuable is the ability of DPA to allow the clinician to manage his patients on therapy. Serial measurements allow the clinician to eliminate ineffective therapy or to modify dose. This reduces unnecessary cost and risk to patients and provides positive patient feedback for complex therapies.

Studies also have been done using the DP3 to measure density at the proximal humerus, knee, and os calcis regions. These measurements also may be useful in orthopedic applications.

Sources/ Dosimetry

The DP3 utilizes ^{153}Gd (1 Ci); source life is 18–24 months. Minimal training is needed to obtain the regulatory agency licensing that is required for possession of ^{153}Gd. Licensing for the LUNAR GD series enables the user to obtain sources from several suppliers. Average patient dose is typically less than 6 mrem with *no* gonadal dose; operator dose is also negligible.

Specifications

Power:
120 VAC ± 10%/8.5A/60Hz or
220 VAC ± 10%/4.3A/50Hz

Temperature:
10°C–35°C (50°F–95°F)
$\Delta T < 8°C/hr$

Humidity:
20–80% non-condensing

Scan table (LWH):
183 cm × 82 cm × 69 cm
(72″ × 32″ × 27″)

Operator console (LWH):
152 cm × 76 cm × 69 cm
(60″ × 30″ × 27″)
(Optional smaller sizes)

Total weight:
242 kg (532 lbs)

LUNAR

916 Williamson Street
Madison, Wisconsin 53703
(608) 258-8545

9/85-10

A Proven System

Since its commercial introduction in 1980 the LUNAR DP3 spine/femur scanner has become the international standard for dual-photon absorptiometry. This dual-photon scanner is in use in over 90% of all clinical facilities offering dual-photon absorptiometry, as well as in nearly all major research centers. These institutions have documented that the DP3 not only is accurate, precise, and easy to use, but that it provides unparalleled diagnostic sensitivity, high patient throughput, precise serial measurements, and extreme reliability. And these advantages are backed by superb support and service from a company dedicated wholly to excellence. ASK A USER and discover why LUNAR is the world leader in bone measurement.

Advanced Hardware

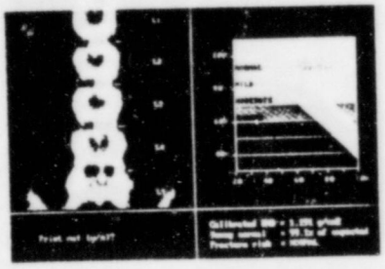
LUNAR's solidly crafted instrumentation assures dependable performance and maximum throughput with minimum space requirement. The DP3 utilizes the widely accepted IBM-XT or IBM-AT computers. These computers feature high-resolution color graphics, hard disk storage, and multi-tasking capability. A multi-tasking capability allows for a second patient scan to be done while analysis is being completed on the first patient. It's even possible to operate several scanners from one computer. This maximizes patient throughput and allows system expansion. Compatibility with hundreds of IBM software packages adds the business capabilities of word processing, databases, spreadsheets, patient accounting, and statistics.

Twenty Five Years of Experience

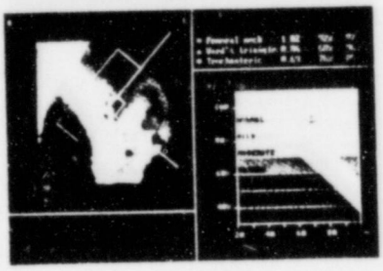
The DP3 scanner was first developed and tested at the University of Wisconsin Bone Mineral Laboratory in the 1970's by the medical physics researchers who introduced both single and dual-photon absorptiometry. The continued work of those researchers at LUNAR ensures that you will receive the most advanced, precise and clinically relevant instrumentation.

Solid Support, Reliable Service

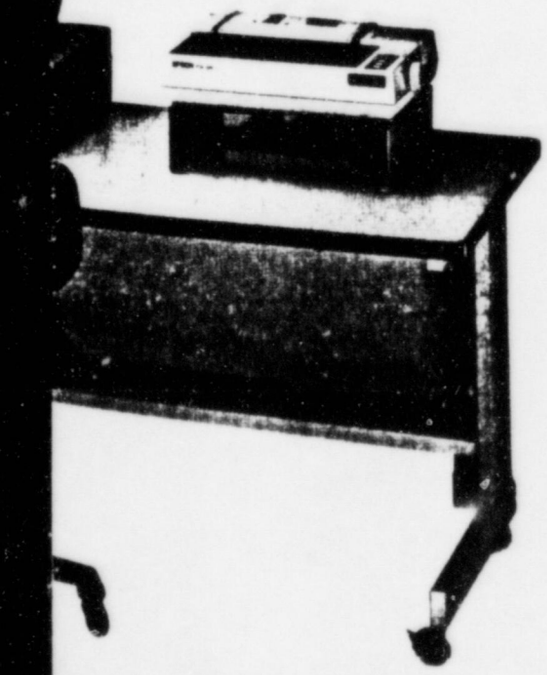
LUNAR is dedicated to customer support. Our experienced staff helped LUNAR become the largest manufacturer of bone densitometers. We provide extensive application support, a complete one-year warranty, and prompt service. Our unique LUNAR INFORMATION NETWORK offers fast assistance as well as information about current events and research findings via telephone modem. LUNAR's program of FREE SOFTWARE UPDATES ensures that all systems are kept at state-of-the-art capability.



Spine Results



Femur Results



Sophisticated Software

Over ten years of dedicated research and clinical testing are evident in the sophistication of the DP3 software. Processing of the count-data minimizes technical errors by use of corrections for dead-time, spillover, background, beam hardening and scatter.

Advanced menu-driven software leads the operator through the measurement procedures and all analysis. The process has been automated to minimize subjective operator decision which increases precision error. However, operator overrides are possible at all steps of analysis with a single keystroke using the menus provided. The automated routines of the DP3 include:

—Bone edge and baseline selection
—Automatic location of vertebral bodies
—Automatic location of femoral regions of interest
—Calculation of results
—Comparison with normal controls
—Calculation of fracture risk
—Graphic presentation of results
—Permanent patient records
—Quality control/calibration

Lumbar Spine Scan

Scans of the lumbar spine are most useful for early diagnosis and management of most types of metabolic bone disease, including osteoporosis. The entire procedure—including data collection, analysis, and hard copy printing—typically takes less than 20 minutes with the DP3.

Other measurement modes (including 7-minute survey scans and 32-minute high resolution scans) offer flexibility for special clinical needs. Intelligent software control allows for on-line location and tracking of the spine as well as on-line graphic display. This reduces the required scan area, scan time and patient radiation exposure.

Results are given for each vertebral body and all combinations of vertebrae to allow exclusion of abnormalities and normalization of each area. The analysis also indicates which vertebral bodies are abnormally small (as one indication of possible fracture) and provides a correction for this.

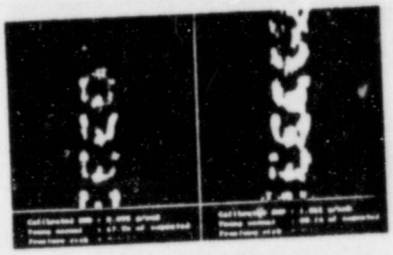
Proximal Femur Scan

A unique system of data collection and analysis allows the DP3 to reliably select regions of interest in the proximal femur despite the large anatomical variations among patients. The DP3 offers analysis of the femoral neck, trochanter (site of 40% of fractures) and Ward's Triangle (highest correlation to strength).

Scan Results

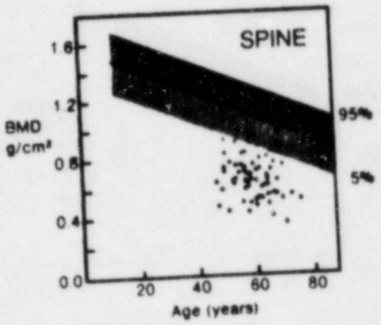
Spine and femoral densities are given not only in calibrated mineral mass or density, but in terms of departure from normality. A large database of normal values provides a ready comparison to young normal (peak bone mass), and to the expected age-related decline. The fracture risk is directly specified. An attractive graphic display (on both screen and printout) of these comparisons aids clinical interpretation.

Only DPA Effectively Monitors Therapy

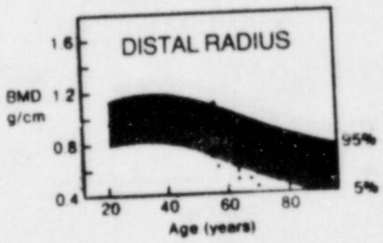


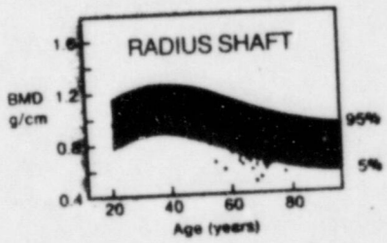
Courtesy of Malcolm Powell, M.D., San Francisco

Only DPA Aids Diagnosis of Osteoporosis



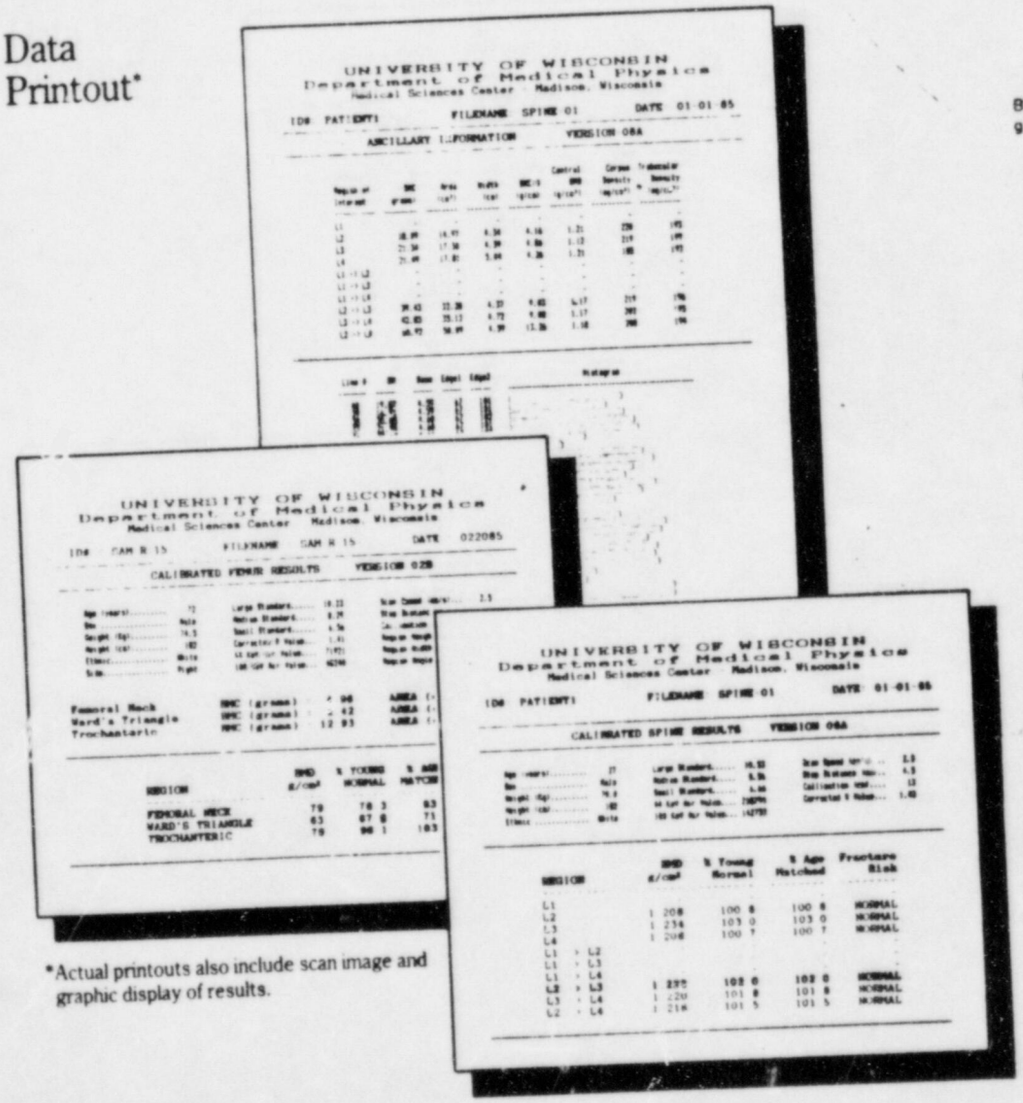
DPA of Spine . . . versus SPA of Radius





Adapted from Wahner, H. W.; Dunn, W. L.; and Riggs, L. 1983. *Seminars in Nuclear Medicine.* 13:282-289.

Data Printout*



UNIVERSITY OF WISCONSIN
Department of Medical Physics
Medical Sciences Center Madison, Wisconsin

ID# PATIENT1 FILENAME SPINE 01 DATE 01-01-85

ANCILLARY INFORMATION VERSION 08A

UNIVERSITY OF WISCONSIN
Department of Medical Physics
Medical Sciences Center Madison, Wisconsin

ID# CAM R 15 FILENAME CAM R 15 DATE 022085

CALIBRATED FEMUR RESULTS VERSION 02B

Femoral Neck
Ward's Triangle
Trochanteric

UNIVERSITY OF WISCONSIN
Department of Medical Physics
Medical Sciences Center Madison, Wisconsin

ID# PATIENT1 FILENAME SPINE 01 DATE 01-01-85

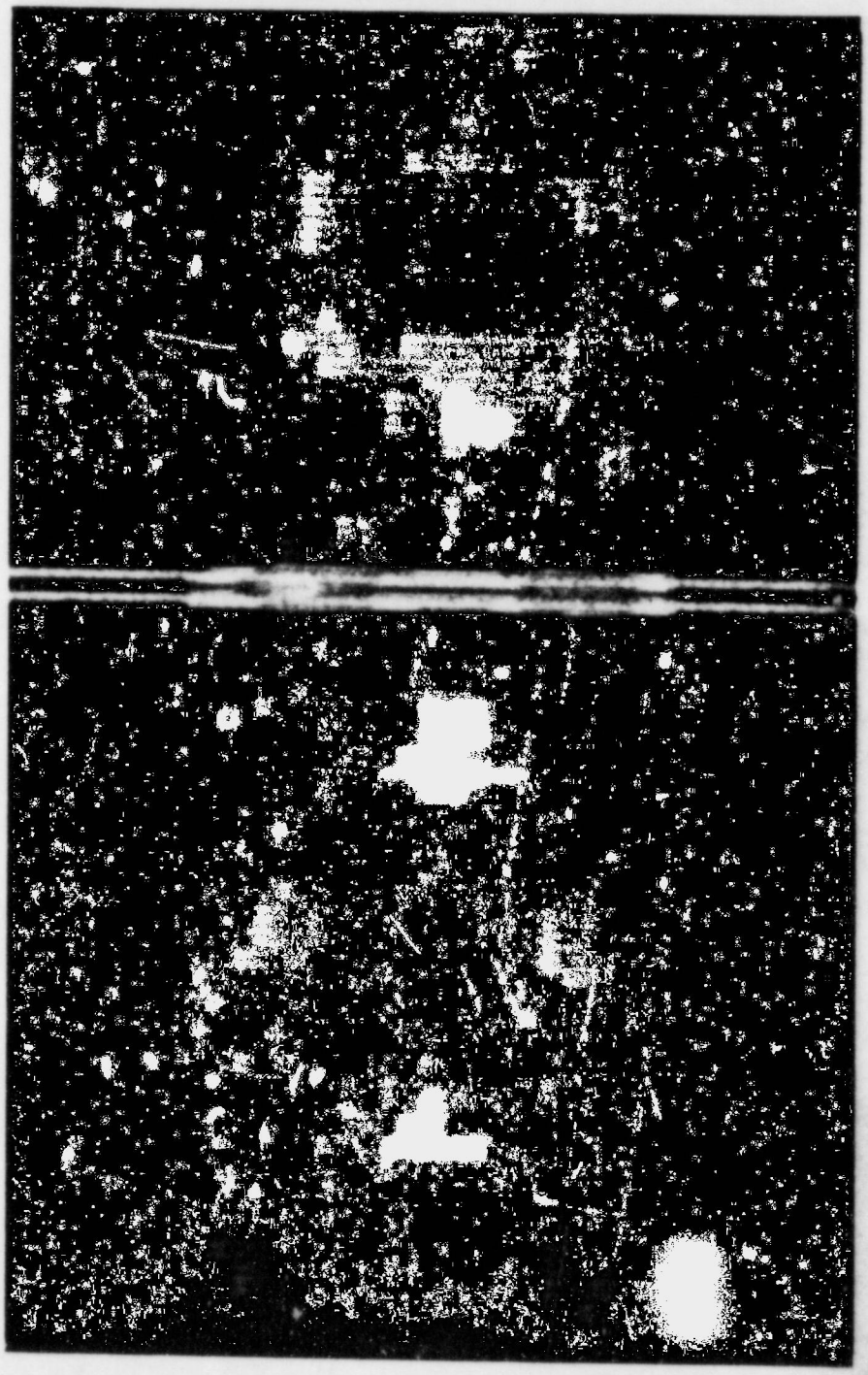
CALIBRATED SPINE RESULTS VERSION 08A

REGION	BMD g/cm²	% Young Normal	% Age Matched	Fracture Risk
L1	1.208	100.8	100.8	NORMAL
L2	1.234	103.0	103.0	NORMAL
L3	1.206	100.7	100.7	NORMAL
L4				
L1 - L2				
L1 - L3				
L1 - L4				
L2 - L3	1.232	102.8	102.8	NORMAL
L2 - L4	1.220	101.8	101.8	NORMAL
L3 - L4	1.216	101.5	101.5	NORMAL

*Actual printouts also include scan image and graphic display of results.

THE NORLAND DICHROMATIC BONE DENSITOMETER

ADVANCED TECHNOLOGY FOR AXIAL BONE ANALYSIS



OUTSTANDING FEATURES OF THE ADVANCED NORLAND 2600 SECOND GENERATION, DUAL BEAM BONE DENSITOMETER

1. MultiProcessor Computer Design with a microprocessor to control the scanning functions plus an IBM-PC-XT Color Graphics Computer with 10 megabyte disk and 640K of memory. This feature makes it possible to Simultaneously Scan a patient While Analyzing the Data From a Previous Scan on the IBM system. The IBM-AT is available as an option with 20 megabyte hard disk and 1.2 megabyte floppy disk drive.

2. One instrument for Lumbar, Femur, and Whole Body Calcium Measurements. New Developments also indicate the potential to measure Density of Kidney Stones and other calcified tissue. The 2600 will measure any bone in the body.

3. Accurate Laser Positioning System enables easy and precise beam positioning anywhere on the 30" x 96" scanning table. Laser actually indicates position of beam to select start and end of scan positions.

4. Unique New Femoral Scanning Technique actually scans any angle so the femur can be scanned at 90 degrees to the femoral neck while the patient is lying parallel to the length of the table. The results require no angular correction and are more accurate and precise than competitive instruments.

5. Programmable Scanning Rates allow user to select pixel size resolutions from 0.1mm to 99.9mm and scanning speeds from 1.0mm to 30mm per second. These translate into lumbar scanning speeds as fast as 7 minutes and as slow as one hour for maximum detail and spatial resolution.

6. Hand Held Controller allows operator to set up the patient and scanner while standing at the patient's side rather than at the computer console.

7. High Resolution Color Graphics Monitor displays detailed density images of the spine, femur and skeleton in 16 different colors selectable by the operator and far superior to single color dot density images.

8. Color Graphics Printer actually provides hard copy color printouts of the color images with Higher Resolution Than The Computer Monitor. To increase the efficiency of the computer system the printer is equipped with a buffer memory that allows the printer to operate simultaneously while the IBM is used to analyze another patients data or set up another scan.

9. Exclusive "BONESTAR" Software System includes patient data base management system for rapid storage and retrieval of up to 1000 patient files on the 10 megabyte disk. 20 Megabyte or 35 megabyte disks are also available for proportionately larger patient capacities. Each patient's file includes details of patient history and essential management facts.

10. **Four Different Display and Analysis Modes** include unique new features for clinical use.

    A. Vertebral analysis to characterize the density of total vertebrae.
    B. Line scan overview to quantify density of a single line scan.
    C. Line scan profile view with detail of bone density displayed in a point by point profile display.
    D. **Unique Local Region of Interest** cursor to examine intra-vertebral locations or kidney stones and calcified tissue.

11. Easy to learn menu driven software architecture is very **"User Friendly"**.

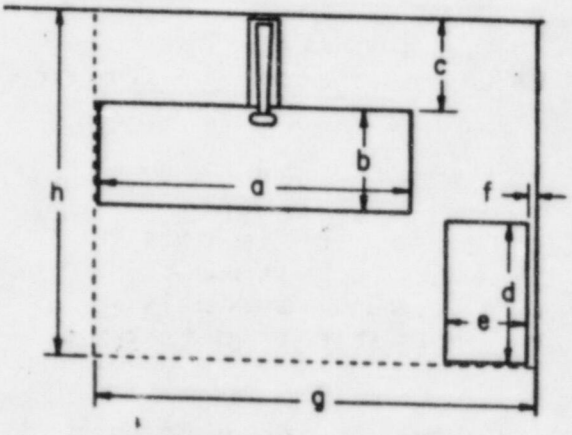
12. **Extra Safe Radioisotope Capsule** with a built-in shutter that can only be opened by installing in the densitometer.

13. **Comprehensive Diagnostic Software** to test both the scanner system and electronics as well as the IBM-PC, which enable prompt and very special analysis of system problems.

14. Complete **Two Day Installation and Training** given at user's facility.

15. **Automatic Calibration and Discriminator Settings** using the full gamma energy spectrum are also included in the Bonestar package.

NORLAND MODEL 2600 PHYSICAL DIMENSIONS



a	SCANNER UNIT LENGTH	243cm (96")
b	SCANNER UNIT WIDTH	76cm (30")
c	SCANNER UNIT MINIMUM DISTANCE FROM WALL	76cm (30")
d	CONTROL/ANALYSIS UNIT LENGTH	121cm (48")
e	CONTROL/ANALYSIS UNIT WIDTH	76cm (30")
f	CONTROL/ANALYSIS UNIT MINIMUM DISTANCE FROM WALL	5cm (2")
g	TOTAL WORK AREA LENGTH	355cm (140")
h	TOTAL WORK AREA WIDTH	274cm (108")

POWER REQUIREMENTS FOR 2600:

120 Volts, 7.5 Amps.

BETA DIAGNOSTICS, INC. 509 McMILLEN ST. FORT ATKINSON, WI 53538
414/563-9341

THE NORLAND DIGITAL BONE DENSITOMETER

A SIGNIFICANT ADVANCE IN BONE QUANTIFICATION

VERSATILITY IN SCAN SITES

Typically, the Bone Densitometer is used to measure the bones of the forearm, but it 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 skeleton. The radius is also an easy bone to measure.

With an optional finger positioning system, the Bone Densitometer can measure the phalanges, a site often monitored in renal osteodystrophy. Fitted with the infant positioning system, the Bone Densitometer can measure the ulna, tibia, fibula, or the humerus in newborn infants. The Bone Densitometer can also be adapted to scan animals such as the femur of the laboratory rat, the tibia of the beagle, or the metacarpal of the horse. Specific positioning systems allow accurate repositioning of the scan site.

THE NORLAND DIGITAL BONE DENSITOMETER

APPLICATIONS

- To any medical specialty concerned with bone demineralization — as in osteoporosis — and for monitoring the response to therapy.[6,7]
- To nephrologists for monitoring bone loss in early renal disease — during chronic dialysis — after transplantation.[8,9]
- To pediatricians and neonatalogists for monitoring delayed bone mineralization and for investigating the effect of therapeutic measures.[10]

Photo courtesy of Milton Werthman, M.D., of Washington Hospital Center of Washington, D.C.

Photo courtesy of Brian J. Awbrey, M.D., of University of North Carolina at Chapel Hill, Chapel Hill, North Carolina

- To laboratory researchers for rapid and accurate in vivo or excised measurement of bone mineral in the laboratory rat, dog, or rabbit.[11,12]
- To researchers monitoring the relationship between bone mineral content and bone strength in the race horse.[13,14]
- To investigators performing population surveys,[15] studying inheritance patterns,[16] or doing nutritional research,[17] exercise studies[18] or pharmaceutical evaluations.[19]

OPTIONAL COMPONENTS

- **Compact High Resolution Printer**

  Four different modes of printed records are provided when using the Bone Densitometer with its optional printer. These printouts range in content from basic scan information to the entire CRT display including bone profile and scan data.

- **Disk Memory Unit**

  The addition of a disk memory unit to the Bone Densitometer enables permanent storage of bone measurement information on diskettes. Data may be retrieved and displayed on the CRT for examination and/or computation providing a valuable aid in serial patient measurement.

- **Scanning Positioning Systems**

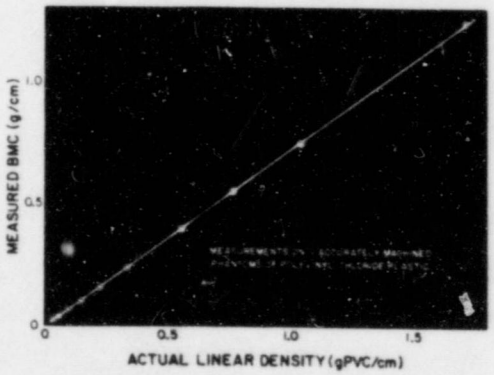
  Optional scanning positioning systems are available to adapt the Bone Densitometer for measurement of finger bones, infant subjects and various animals.

  - Finger positioning system
  - Infant positioning system
  - Small animal positioning system
  - Excised bone positioning system

BONE MINERAL CONTENT:

ACCURACY AND PRECISION

In the Bone Densitometer, accuracy is determined by two factors, the linearity of response of the instrument and the absolute accuracy of its calibration. The linearity of response was evaluated in characterizing the perfórmance of this instrument. Over a range of bone sizes from 0.020 g/cm to 1.300 g/cm, the Bone Densitometer is linear to within 0.0036 g/cm. Note that this corresponds to considerably better than one percent over the range of bone mineral in the radius.

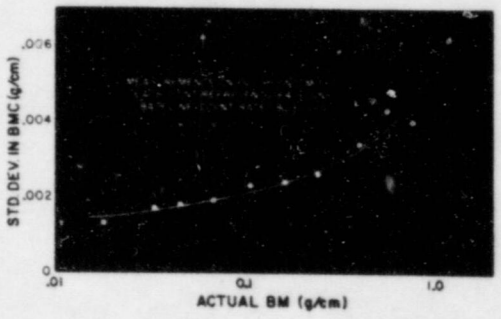


Linearity in Bone Mineral Content

Absolute accuracy of its calibration is dependent on studies done at the University of Wisconsin Bone Measurements Laboratory in the early 1970's. The calibration is through a set of primary standard phantoms which Norland constructed and the Wisconsin group calibrated against ash studies.

Every Bone Densitometer is supplied with a four chamber phantom which is calibrated against the primary standards evaluated by the Wisconsin group.

The major contributor to loss of precision with photon absorptiometry is in the statistical variation in the radiation processes of emission, absorption, and detection. Because these processes follow Poisson statistics, the scatter in the individual photon transmission measurements making up a bone scan is always proportionately greater for lower count rates.

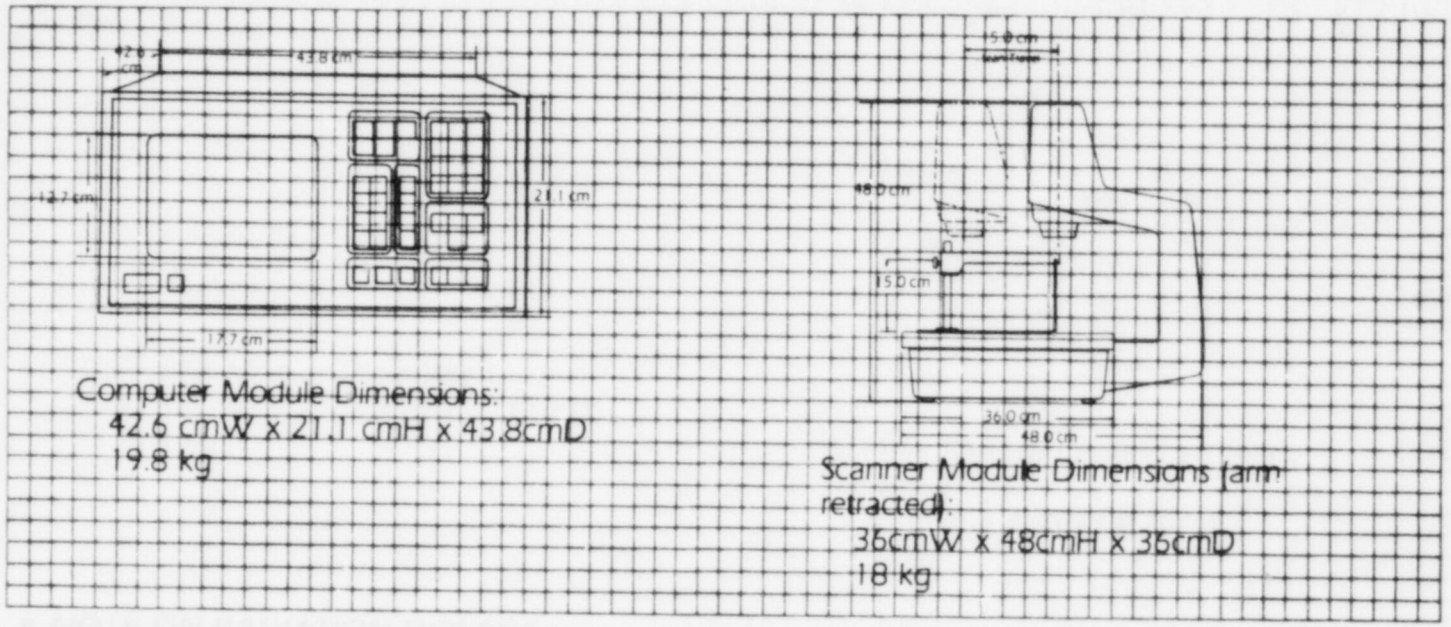


Precision in Bone Mineral Content

As the above data shows, these variations translate into a modest absolute increase in standard deviation in BMC with an increase in bone size.

THE NORLAND DIGITAL BONE Ddensitometer

PHYSICAL SPECIFICATIONS



A NOTE ON RADIATION DOSAGE

Comparing a Bone Densitometer scan with a radiograph 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 useful comparison can be made by considering the total intra-tissue ionization based on relative radiation fields, exposure times, and areas exposed. The results show the total ionization produced within a patient during a set of four densitometer scans is about 1/100 of that delivered by a radiograph of the forearm.

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Norland Corporation maintains a comprehensive technical resource library and applications staff as an aid to investigators. This library and staff are available to investigators seeking information about a specific area of interest. We look forward to receiving your inquiry.

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BONE QUANTIFICATION

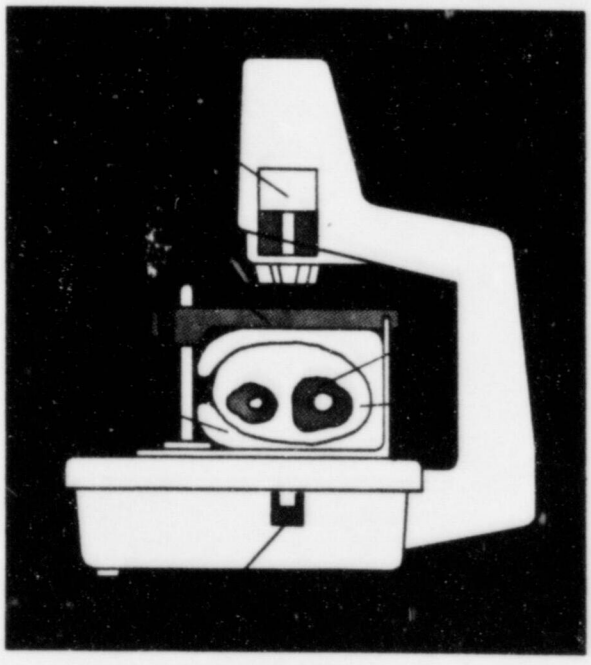
A NEED — A SOLUTION

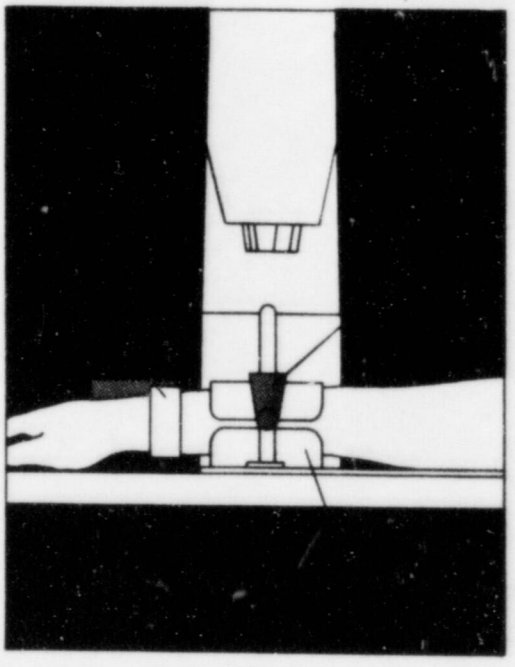
Physicians and clinicians have long recognized the shortcomings of biopsy or radiographic methods for the early detection of bone disease. In 1963, Cameron and Sorenson reported a new in vivo, non-intrusive method for quantifying bone mineral content -- the photon absorption technique.[1] Since then, the technique has grown in sophistication and gained widespread clinical approval.[2,3]

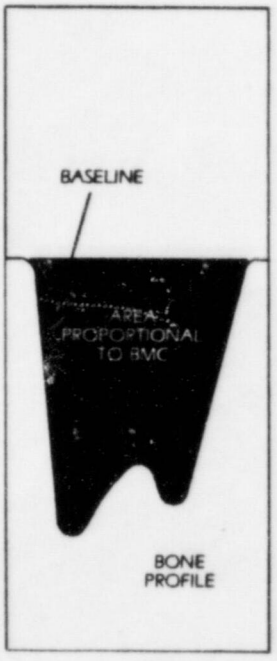
THE PHOTON ABSORPTION TECHNIQUE

This technique replaces the broad energy spectrum of the x-ray beam with a beam of monoenergetic photons. The highly collimated beam passes through the soft tissue and bone of a limb, and its absorption is monitored with a photon detector. A tissue equivalent bag assures a uniform soft tissue thickness surrounding the bone so that attenuation resulting from bone may be identified. The mass of bone mineral present may then be derived from the number of photons absorbed by the bone. A specially designed limb positioning system assures consistent and correct orientation of the limb for screening.[4] This bone measurement technique offers great advances in accuracy, precision, and practical usefulness.

THE NORLAND DIGITAL BONE Ddensitometer







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 Bone 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.[5] Compare this sensitivity to that of the radiograph, which is unable to detect changes before a 30-40% loss in bone mass.[3] In addition, the expanded capacity of this Bone Densitometer allows it to detect and measure bones as small as 0.05 g/cm.

BETA DIAGNOSTICS, INCORPORATED

BETA DIAGNOSTICS, INC.
I-125 RADIOISOTOPE RETURN POLICY

DEC. 1, 1984

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

Your new source is priced with the assumption that your old source will be returned to Beta 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

IN YOUR NORLAND BONE DENSITOMETER.

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

FIG. 1

"Source Assembly AECL C-296 or 178A591A with shipping cap removed 30 degree radiation field illustrated."

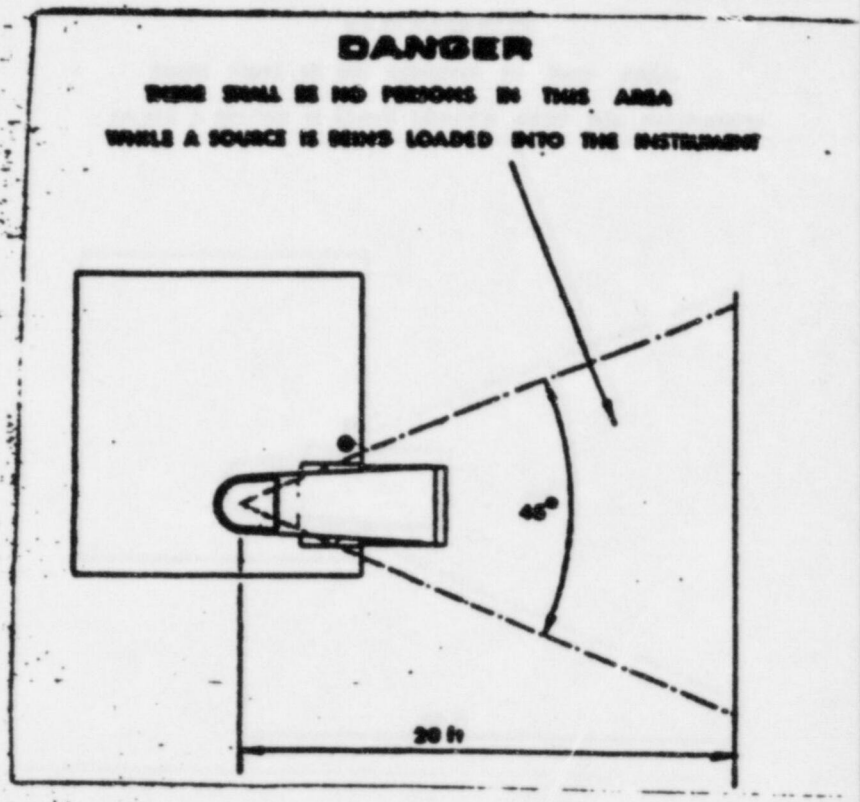


FIG. 2

"Radiation Hazard Area during source loading and unloading."

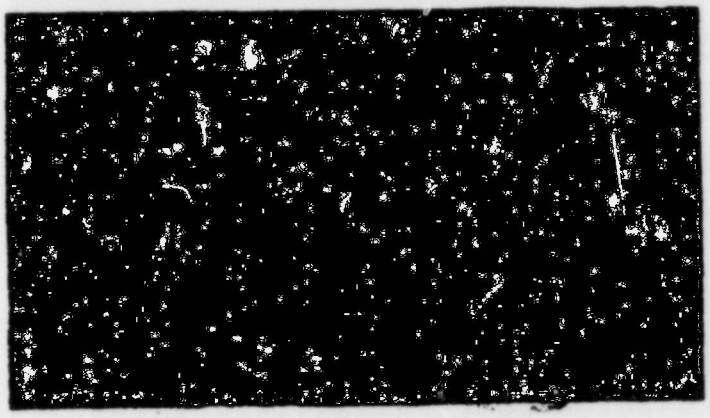
A 200 mCi source delivers a maximum dose rate of approximately 200 mr/min at a distance of 2.5 cm. The protective cover should not be removed until the source is actually installed in the scanner. When installing the source, be sure that there are no persons in the scanner area indicated by Figure 2.

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 back). 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.

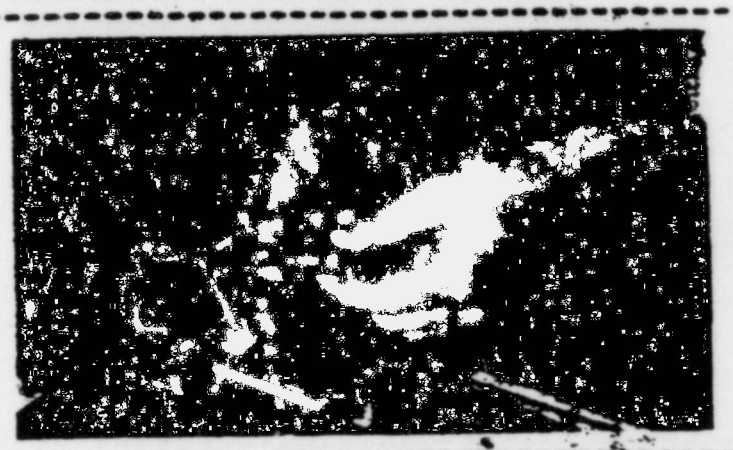
While loading or unloading the source, keep fingers away from the exposed end of the source holder at all times. Do not point the exposed source toward anyone. When removing the source from the scanner, reverse the loading procedure. Be sure to replace the cap on the source holder before tranporting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

PROCEDURE FOR LOADING SOURCE

A. Lift source/shutter door.

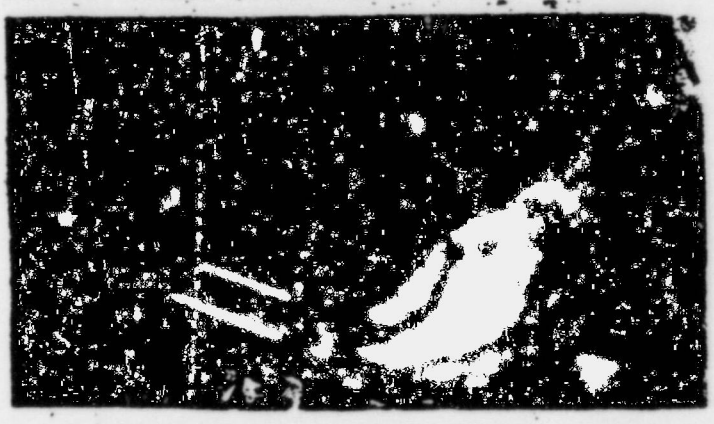


B. Remove source cap. Hold source in position shown.



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

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



BETA DIAGNOSTICS, INC., 210 Madison Avenue, Fort Atkinson, WI 53538, (414)563-9341

CALIBRATION OF INSTRUMENTS

Calibration of Survey Instruments:

A. Survey instruments will be calibrated at least annually and following repair.

B. Procedures and sources have been approved by the State of Maryland, License MD-31-035-01 and U.S.NRC Regulatory Guide 10.8.

C. Survey instruments will be calibrated by a consultant 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.

4. 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.

5. 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.

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.

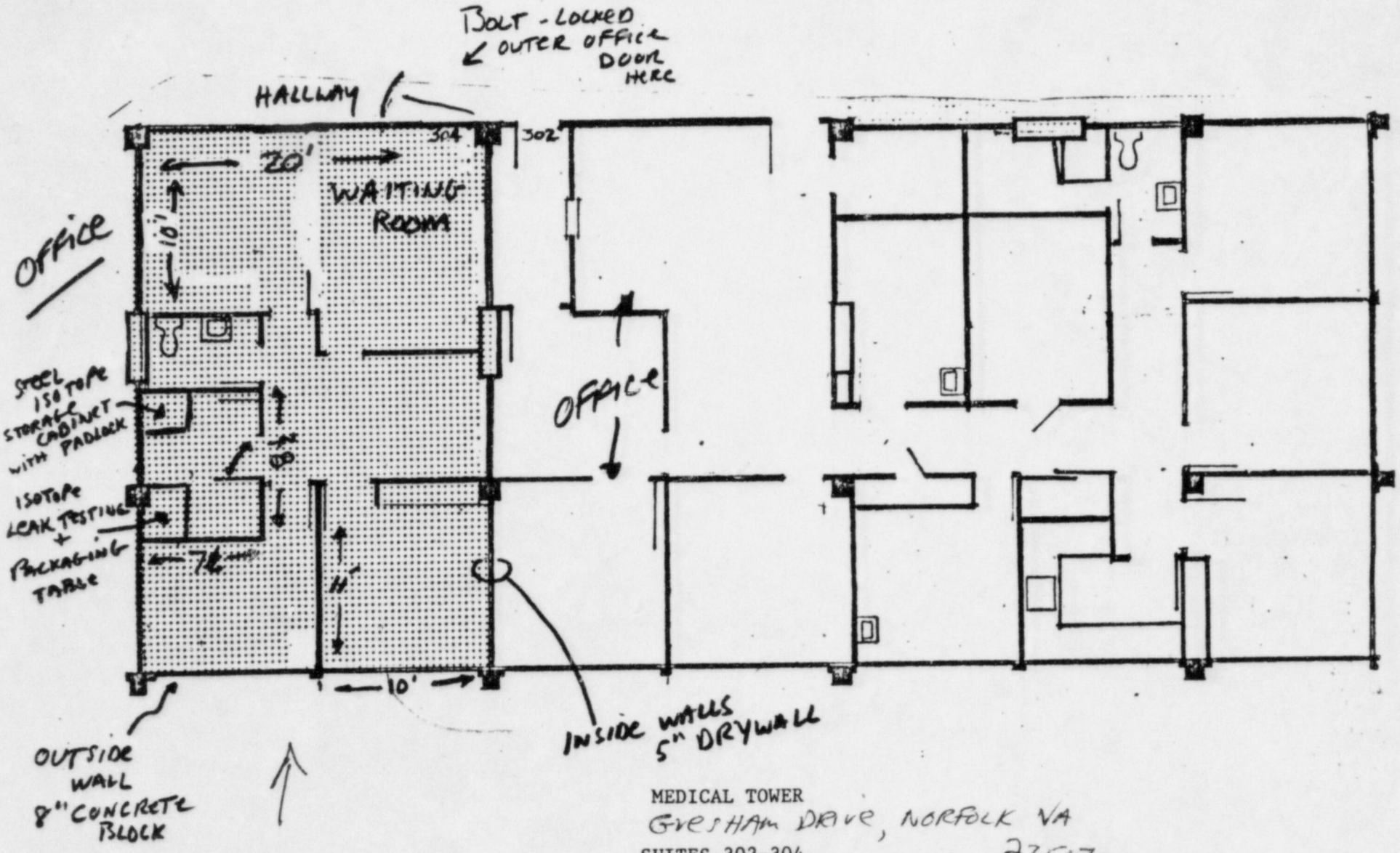
3. Building:

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.



MEDICAL TOWER
GRESHAM DRIVE, NORFOLK VA 23507
SUITES 302-304.
2100 s.f.

SUITE 304 will be used

0 10' 20' 30' 40'
GRAPHIC SCALE

PERSONNEL TRAINING PROGRAM:

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 or stored.

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.

I. 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 RECEIVING 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).

B. The following additional procedures for opening packages will be carried out:

1. Put on gloves to prevent hand contamination.

2. Visually inspect package for any signs of damage (e.g. wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

3. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If > 10mR/hr, stop procedure and notify Radiation Safety Officer.

4. Measure surface exposure rate and record. If >200mR/hr, stop procedure and notify Radiation Safety Officer.

5. Open the package with the following precautionary steps:

   a. Open the outer package (following manufacturer's 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.

   c. Check integrity of final source container.

   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.

7. Monitor the packing material and packages for contamination before discarding.

Item 14
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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 Record". (attached)

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GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

A. Wear disposable gloves at all times while handling radioactive materials.

B. 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.

E. Never remove sources from brass shielding capsules.

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.

G. Appropriate records of serial numbers, dates, leak tests, and shipments of sources will be kept as required in the regulations.

H. Disposal of old sources will be accomplished only by shipping the sources to the supplier, who has agreed to dispose of such sources.

I. 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.

K. 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.

L. 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.

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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: Robert S. Neff, M.D.

Office Phone: 804-461-1688

Home Phone: 804-460-1696

Alternate(s)

Name: Joel A. Mason, M.D.

Office Phone: 804-461-1688

Home Phone: 804-489-8128

Item 16
11/12/84

AREA SURVEY PROCEDURES

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 0.1 mR/hr.

B. A permanent record will be kept of all survey results, including negative results. The record will include:

1. 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.

WASTE MANAGEMENT

The clinic will return used sources in their brass shields, packaged in accordance with DOT and NRC regulations, to the source supplier for disposal.

- - - - - -TO BE TYPED ON FACILITY LETTERHEAD- - - - - -

FOREWORD

Ionizing 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 I

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

PHASE II

Control operational procedures by the user of radiation sources.

PHASE III

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.

_____

Administrator

_____

Date

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

1. 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.

D. Reviewing Instances of Deviation from Good ALARA Practices

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 Safety Officer or his consultant. The Investigational Levels that we have adopted are listed in Table 1 below. These levels apply to the exposure of individual workers.

TABLE 1

	Investigational Levels - (mrems per calendar quarter)	
	LEVEL I	LEVEL II
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:

A. Quarterly exposure of individuals to less than 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.

B. 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

_____

Name (type or print)

_____

Title