

FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved GAO R0557
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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 <div style="text-align: center;"> DRS. ANDERSON, BARBOUR et al 5031 VILLA LINDE PKWY #32 FLINT, MI 48504 </div> TELEPHONE NO. AREA CODE (313) 232-1197	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (if different from 1.a.) INCLUDE ZIP CODE <div style="text-align: center;"> Same </div>
2. PERSON TO CONTACT REGARDING THIS APPLICATION <div style="text-align: center;"> Paul Lauber, M.D. </div> TELEPHONE NO. AREA CODE (313) 762-2000	3. THIS IS AN APPLICATION FOR: (Check appropriate item) a. <input checked="" type="checkbox"/> NEW LICENSE b. <input type="checkbox"/> AMENDMENT TO LICENSE NO. _____ c. <input type="checkbox"/> RENEWAL OF LICENSE NO. _____
4. INDIVIDUAL USERS (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.) <div style="text-align: center;"> Please see attached list labeled Item #4 & 8 </div>	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.) <div style="text-align: right;"> L.R. IRISH, M.D. </div>

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN: N / A	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS: N / A	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES			IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
10 CFR 35.100, SCHEDULE A, GROUP I		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 COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP III			GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP VI					

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. (Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
I-125	Sealed Source	200 mCi	Bone Density Scanner
Please refer to attached Item # 6 b			
8504120053 850321 REG3 LIC30 21-24374-01 PDR		Control No.	77345

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. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE N / A		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One)	
Names and Specialties Attached; and		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)	
Please refer to Item #8 attached.		Appendix H Procedures Followed; or	
8. TRAINING AND EXPERIENCE		X	Equivalent Procedures Attached
Supplements A & B Attached for Each Individual User; and		17. AREA SURVEY PROCEDURES (Check One)	
Supplement A Attached for RSO.		Appendix I Procedures Followed; or	
9. INSTRUMENTATION (Check One)		X	Equivalent Procedures Attached
Appendix C Form Attached; or		18. WASTE DISPOSAL (Check One)	
X	List by Name and Model Number	Appendix J Form Attached; or	
10. CALIBRATION OF INSTRUMENTS		X	Equivalent Information Attached
Appendix D Procedures Followed for Survey Instruments; or _____ (Check One)		THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)	
X	Equivalent Procedures Attached; and	N/A	Appendix K Procedures Followed; or
Appendix D Procedures Followed for Dose Calibrator; or _____ (Check One)		Equivalent Procedures Attached	
N/A	Equivalent Procedure Attached	20. THERAPEUTIC USE OF SEALED SOURCES	
11. FACILITIES AND EQUIPMENT		N/A Detailed Information Attached; and	
X	Description and Diagram Attached	Appendix L Procedures Followed; or _____ (Check One)	
12. PERSONNEL TRAINING PROGRAM		Equivalent Procedures Attached	
X	Description of Training Attached	21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133)	
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		N/A Detailed Information Attached	
X	Detailed Information Attached	22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (Check One)		N/A Detailed Information Attached	
Appendix F Procedures Followed; or		23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
X	Equivalent Procedures Attached	N/A Detailed Information Attached	

24. PERSONNEL MONITORING DEVICES

TYPE <small>(Check appropriate box)</small>		SUPPLIER	EXCHANGE FREQUENCY	
a. WHOLE BODY	<input checked="" type="checkbox"/> X	FILM	R. S. Landauer Jr. & Co.	Monthly
	<input type="checkbox"/>	TLD		
	<input type="checkbox"/>	OTHER <i>(Specify)</i>		
b. FINGER	<input type="checkbox"/>	FILM		
	<input checked="" type="checkbox"/> X	TLD	R. S. Landauer Jr. & Co.	Monthly
	<input type="checkbox"/>	OTHER <i>(Specify)</i>		
c. WRIST	<input type="checkbox"/>	FILM		
	<input type="checkbox"/>	TLD		
	<input type="checkbox"/>	OTHER <i>(Specify)</i>		

d. OTHER *(Specify)*

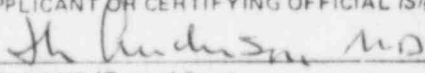
25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL			
NAME OF HOSPITAL <div style="text-align: center;">N/A</div>		b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.	
MAILING ADDRESS		c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.	
CITY	STATE	ZIP CODE	

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED <small>(See Section 170.31, 10 CFR 170)</small>	b. APPLICANT OR CERTIFYING OFFICIAL <i>(Signature)</i> <div style="text-align: center;">  (1) NAME <i>(Type of Print)</i> J. H. ANDERSON, MD (2) TITLE Pres </div>
(1) LICENSE FEE CATEGORY	c. DATE 20 Aug 84
(2) LICENSE FEE ENCLOSED \$ 150.00	

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 Form NRC-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.

ITEM 4 and 8

USERS AND TRAINING AND EXPERIENCE

For training and experience of each of the physicians listed below, please refer to the application for license No. 21-04171-04, issued to McLaren General Hospital, Flint, Michigan

Paul B. Lauber, M.D.

J. L. Anderson, M.D.

L. R. Irish, M.D.

D. A. Barbour, M.D.

L. W. Vergith, M.D.

Douglas M. Dacko, M.D.

ITEM 6 b

DESCRIPTION OF THE SEALED SOURCE -

Please refer to the attached copy of the brochure from ND Medical Products. The model number of the unit that will be purchased from ND Medical Products is ND-1100 Bone Density Scanner.

The source will be used as described in the brochure under "operation". As the source needs to be replaced every 5 months, we request authorization to possess three sources.

The I-125 sealed source, with 200 mCi I-125, is purchased from Atomic Energy of Canada and the model number of the source is C-324. The source is shipped in its 1/4 inch lead collimator, which in turn is placed in a container shielded with 1/8 inch lead. The details of the sealed source are listed below:

- [a] Model No. C-324
- [b] NC Classification : C-34334
- [c] A 200 mCi source will have the activity between 180 mCi and 250 mCi
- [d] I-126 contamination is less than 0.5%

Additional information can be obtained from:

Atomic Energy of Canada Ltd.
Isotope Products Group
413 March Road
P.O. Box 13500
Kanata, Ontario K2K1X8, Canada
Phone No. (613) 592-2790.

The spent sources will be kept in a 6" X 6" X 6" box, shielded with 1/8 inch lead. The box will be kept in the secured cabinet indicated in the attached diagram (Item No.11).

ITEM 9

INSTRUMENTATION

Type of Instrument:	G M Survey meter
Manufacturer:	Ludlum
Model:	14 C
Minimum Range:	0 - 2 mR/hr
Maximum Range:	0 - 2,000 mR/hr
Number of Instruments Available:	One

ITEM #9

ITEM 10
CALIBRATION OF INSTRUMENTS

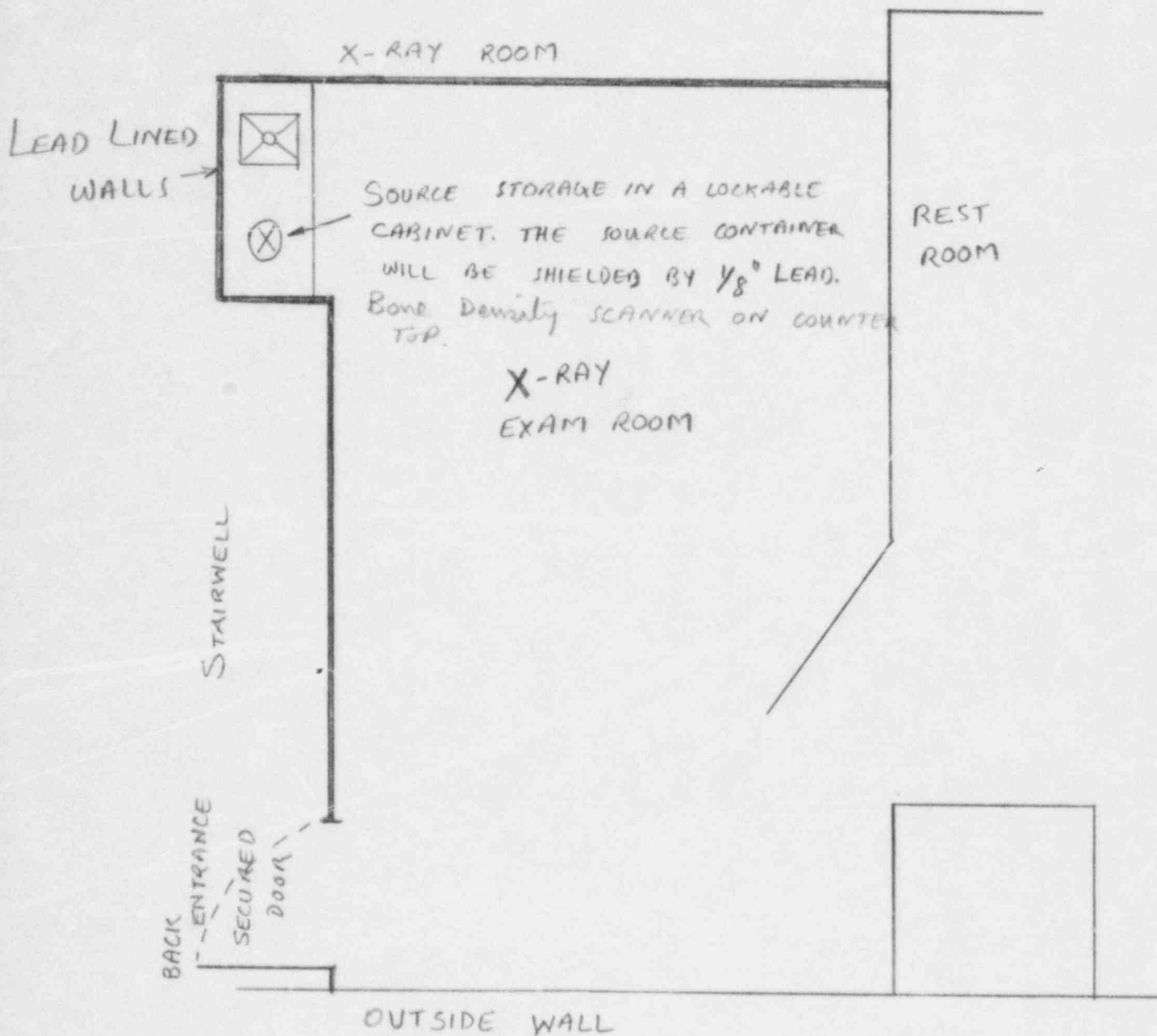
The survey meter will be calibrated annually by Health Physics Associates, Ltd., 3304 Commercial Avenue, Northbrook, Illinois 60062.

The procedure used to calibrate the survey meter is on file with the NRC under License No. 12-09160-01, issued to Health Physics Associates, Ltd.

When the survey meter is sent for repair or calibration, a "loaner" survey meter will be obtained.

A reference check source will be used to check the constancy of the GM survey meter prior to use. If a reading with the same geometry is not within $\pm 20\%$ of the reading measured after calibration, the instrument will be recalibrated.

ITEM No. 10



ITEM # 11 (4/84)

ITEM 12

PERSONNEL TRAINING PROGRAM

The technologist(s) will be instructed in the use of the ND 1100 Bone Density Scanner and the radiation safety aspects of the I-125 sealed source. The instructions will be provided by a representative of the ND Medical Products and will include the configuration of the source, safe removal of the source, safe storage of the source, and the installation of the source in the Bone Density Scanner.

ITEM No. 12

ITEM 13

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

The sealed source will be ordered by one of the licensed physicians listed on this application.

The sealed source will be delivered directly to the X-Ray receptionist who will insure that the source is immediately secured in the storage place indicated on Item No. 11. The physician will be notified immediately of the receipt of the source.

ITEM 14

PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS

The package containing the sealed source will be surveyed at surface and at three feet, and the sealed source in its lead shielding container will be placed in the storage place.

ITEM No. 14

(4/84)



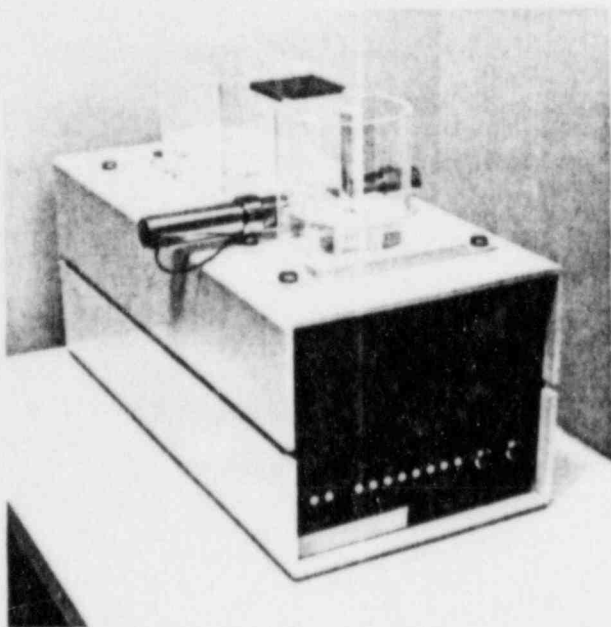
ND Medical Products

Nuclear Data Inc.
Golf and Meacham Roads
Schaumburg, Illinois 60196

Telephone (312) 884-3636

PRODUCT INFORMATION

ND 1100 BONE DENSITY SCANNER



Description

The ND 1100 Bone Mineral Scanner is a versatile and reliable instrument for the determination of Bone Mineral Content. The ND 1100 is also a highly reproducible method for the estimation of total body calcium.

The physiological rate of change of Bone Mineral Content is very slow, typically 1-3% per year. This slow but significant rate of change requires high accuracy and excellent reproducibility. The rugged construction and advanced engineering of the ND 1100 Bone Mineral Scanner ensures both.

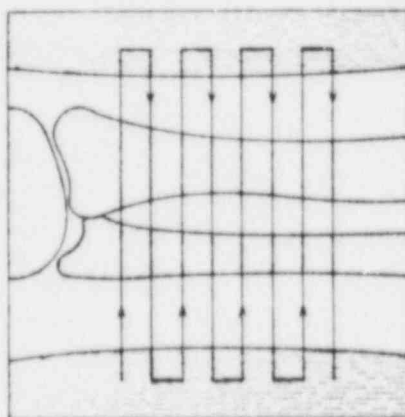
Features

- Microprocessor controlled
- Excellent reproducibility
- Operational simplicity
- Automatic positioning
- Self-calibration
- Compact construction
- Read-out of horizontal and vertical position
- Built-in RS 232 serial interface
- Optional computer
- Recycling self-test
- Autotuning

Application

The measuring of bone mineral content by the two-dimensional photon absorptiometry method is a simple non-invasive way to determine changes in total body calcium. Total body calcium can be quantified in at least two ways. The first is whole body counting of ^{45}Ca after neutron activation. This method requires expensive equipment only present in a few and specialized medical centers.

Another method is the measurement of Bone Mineral Content in the forearm by scanning the distal part of the radius and ulna. This latter method has shown good correlation to total body calcium measurement, is inexpensive, practical and fast.



Operation

The patient grasps the handle in the water-filled acrylic container whereby the forearm is automatically positioned. A highly collimated low intensity photon beam from the essentially monochromatic ^{125}I Gamma-source is scanned a preset number of times across the forearm in a rectilinear format. The photons passing through the water-filled container are detected by a scintillation detector placed opposite the source. A high degree of accuracy is assured due to the construction of the container which maintains a constant thickness across the measuring path.

Data from each scan are automatically transferred to the peripheral device through the built-in RS232 serial interface for calculation and data presentation by the HP-85 computer. The mean value of six successive scans is computed with excellent long term reproducibility of the Bone Mineral Content measurement.

The HP-85 desk-top computer allows conversational communication between the instrument and the operator through monitored messages and keyboard response. In addition to the standard Bone Mineral Content software, the HP-85 offers the possibility for user developed programs.

The computer has a built-in graphic and alphanumeric monitor for presentation, listing and printing. The magnetic tape stores all programs and raw data for off-line calculations.

SPECIFICATIONS

Scanning

- Drive: Microprocessor controlled stepping motors.
- Speed: 2mm/sec.
- Height*: 0-9 cm, stops automatically 1 cm above the arm.
- Spacing*: 0-9 mm with 1 mm steps.
- Number of scans*: 1-9 scans after auto-positioning.

*Controlled from external computer.

Position

- Readout on front panel of horizontal as well as vertical position. Manual positioning of the source and detector.

Source

- Type: ^{125}I typically 2-4 GBq (50-100 mCi).
- Dimensions: 0.3 x 10 mm.
- Active diameter: 0.1 mm.
- Energy: 27-35 keV, X-rays.
- Half-life: 60 days.
- Holder: Cylindric with lead shielding and inductive safety switch.
- Collimation: 0.2 mm x 5 mm.

Detector

- Type: 0.5" x 0.25" NaI(Tl) detector with 0.75" photomultiplier. Optimized for ^{125}I .
- Collimation: Slot 2 mm x 6 mm, length 10 mm.

Data output

- RS-232 interface for external computer or printer.

Scaler/Analyzer

- Preset level for ^{125}I .
- Adjustable window width.
- Maximum 1×10^6 cps.
- Adjustable high voltage.

Acrylic water reservoir

- Inner length: 480 mm.
- Inner height: 140 mm.
- Inner width in measuring area: 70 mm.
- Length of measuring area: 140 mm.

Power requirements

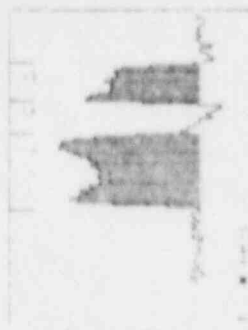
- 220V/50 Hz or 110V/60 Hz.
- Single phase, grounded.
- Consumption: 200 W.

Dimensions

- Height: 280 mm. (9")
- Width: 330 mm. (13")
- Length: 690 mm. (27½")
- Weight: 30 kg. (66 lb.)

Typical Print-out

DATE: 11/11/84
TIME: 11:11
NUMBER OF SCANS: 1
SOURCE: 125I
ANALYST: J. J. J.

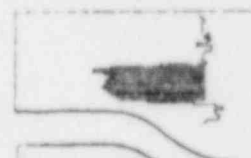


SRC-1X 0.155 GRAMS CH
SRC-2X 1.15X GRAMS CH
BW-1X 12.0 MM
BW-2X 12.0 MM
SPALX 15.2 MM



SRC-1X 0.176 GRAMS CH
SRC-2X 1.216 GRAMS CH

BW-1X 12.0 MM
BW-2X 12.0 MM
SPALX 15.2 MM



BW-1X 12.0 MM
BW-2X 12.0 MM
SPALX 15.2 MM



SRC-1X 1.154 GRAMS CH
SRC-2X 1.282 GRAMS CH

BW-1X 12.0 MM
BW-2X 12.0 MM
SPALX 15.2 MM

SRC-NORM: 25.4 UNITS

Specifications subject to change

ND Medical Products

Cable NUDATA • Telex 28-2416

Nuclear Data Inc. • Golf and Meacham Roads • Schaumburg, Illinois 60196 • Telephone (312) 884-3636
ND Medical Products • 221 Felch Street • Ann Arbor, Michigan 48103 • Telephone (313) 665-9777

Amsterdam • Atlanta • Boston • Chicago • Denver • Frankfurt • London • Los Angeles • New York • San Francisco • Seattle • Stockholm • Washington, DC

PRODUCT INFORMATION

ND Medical Products
Nuclear Data Inc
Golf and Meacham Roads
Schaumburg, Illinois 60196
Telephone (312) 884-3636



ND1100 Bone Density Scanner

Precision, Measurement of Total Body Calcium and Clinical Applicability

Bone mineral content has been shown to decline with age, especially in females following menopause. Severe bone mineral loss is associated with the high incidence of fractures in women over 65 years of age.¹ Measurements of the annual rate of bone mineral loss indicate that approximately one to two percent of the total body bone mass is lost per year.² This loss rate defines the measurement precision necessary for diagnosis and treatment of various disturbances of calcium metabolism.

To adequately assess the changes in bone mineral content, both the precision and the long-term reproducibility of any bone mineral measurement must be on the order of one percent. This precision can now be obtained using the ND1100 Bone Density Scanner. This unit uses a two-dimensional scanning technique which also provides a means of measuring total body calcium content.

Precision

The precision of measurement obtained using the ND1100 has been shown to be approximately one percent for 19 normal subjects over a period of one year.³ Figure 1 illustrates the measured minimum calcium difference in percent and in grams for a fixed total body calcium of 750 grams. These values are also expressed in mg calcium per day

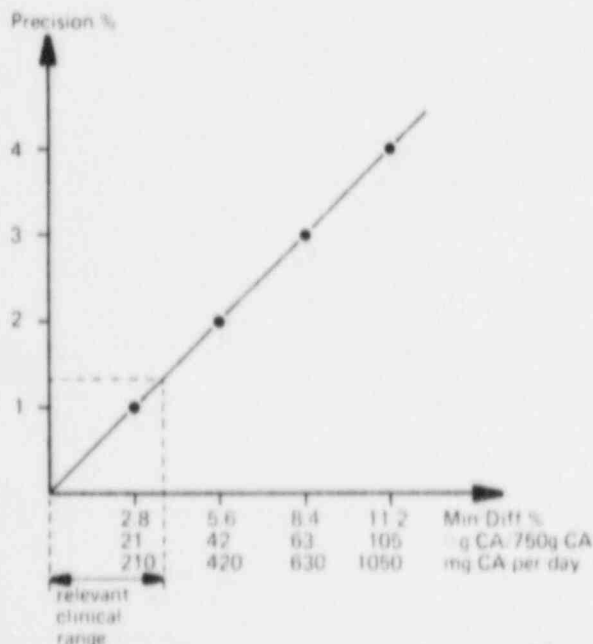


Figure 1. Long-term precision calculated in 19 normal patients.

for a 100-day period. Since the size of the daily mean positive calcium balance required for successful treatment of osteomalacia is often not higher than 300 mg per day, necessitating a long-term precision of 1.4%, the ND1100, with a measurement precision of 1%, is within the relevant clinical range.

Measurement of Total Body Calcium

The ND1100, which uses a forearm measurement to determine bone mineral content (BMC), provides a simple and precise method of measuring total body calcium. Gotfredsen, et al⁴ have shown that a strong correlation exists between the measured bone and the total body bone mineral (TBBM) content. Figure 2 illustrates that it is possible to estimate total body calcium with a high degree of accuracy from a measurement on the distal part of the forearm in groups of patients with different calcium metabolic disorders.

1. Rheumatoid arthritis with (●) and without (○) steroid treatment.
2. Osteoporosis (*).
3. Anticonvulsant osteomalacia: phenytoin (▲) and carbamazepine (△) treated.
4. Patients operated for peptic ulcer: op. a.m. Billroth I (■); a.m. Billroth II (□); and Vagotomy (⊕).
5. Normals (+).

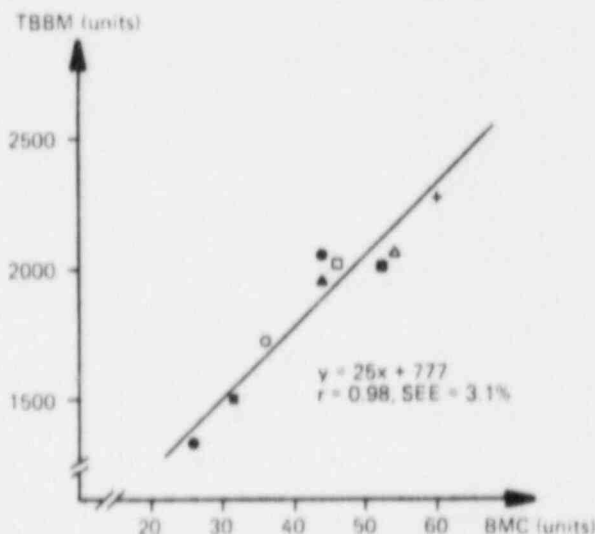


Figure 2. Relation between total body bone mineral (TBBM) and BMC in 9 study populations (including 56 healthy subjects and 150 patients).

Clinical Applicability

Since bone mineral loss is approximately one to two percent per year, measurement of bone mineral content during the course of treatment requires an instrument with the precision and reproducibility of the ND1100. Figure 3 illustrates measured bone mineral content as a function of time and treatment for a study population of 94 women, half receiving treatment and half receiving a placebo. The figure indicates that the loss of bone mineral content can be reversed with treatment.⁵

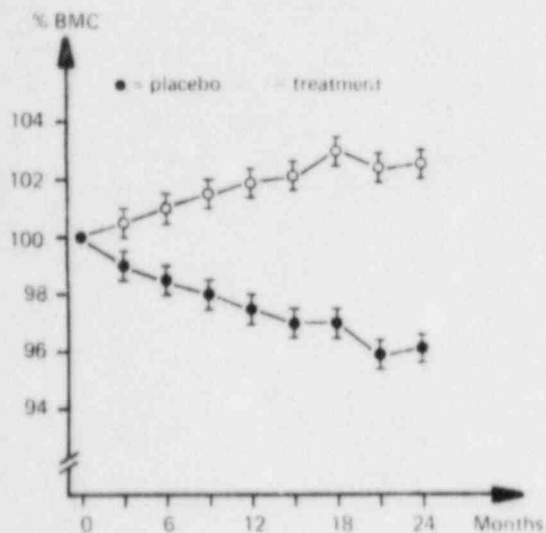


Figure 3. Percent bone mineral content (% BMC) as a function of time and treatment in 94 women shortly after menopause.⁵

References

1. Smith, et. al. J. Clin. Invest. 58, 716 (1976)
2. Mazess, R.B. and Christiansen, C., Human Biol. 54, 343 (1982)
3. Christiansen, et. al. Scand. J. Clin. Lab. Invest. 37, 321 (1977).
4. Gotfredsen, et. al. J. Comput. Assist. Tomography, 1983, in press.
5. Christiansen, et. al. Lancet (1981) 459.

ITEM 16
EMERGENCY PROCEDURES

If the source is stolen or lost, the NRC will be notified as specified by 10 CFR 20.402.

Every effort will be made to locate the source.

ITEM No. 16

ITEM 17

AREA SURVEY PROCEDURE

The Bone Density Scanner containing the I-125 sealed source will be surveyed once a month. A low level GM survey meter with probe window open will be used to conduct the surveys. The readings will be taken at surface and at 12 inches from the surface of the scanner.

If a spent source is stored for decay, radiation levels will include the surveys of the source container.

Records will be kept.

ITEM 18
WASTE DISPOSAL

The "spent" I-125 sealed source will either be stored for decay at our facility or will be returned to Atomic Energy of Canada for disposal.

If the source is kept on site for decay, it will be stored in the lead container for a minimum of 10 half-lives, when it will be removed from all of its lead shielding and will be monitored in contact with a low level GM survey meter with probe window open. If the radiation levels are those of natural background in unrestricted areas, the sealed source will be discarded as routine waste after defacing any "radioactive" symbols that may be on the source. If the radiation levels are above natural background, the source will be stored in its lead shielding until the levels are at background levels.

The records of disposal will be maintained:

- [a] If the sealed source is shipped for disposal as indicated above, the date of disposal will be recorded. The source will be shipped in accordance with specifications from Atomic Energy of Canada.
- [b] If the source is decayed on site, the records would indicate the date of disposal, GM survey reading and the initials of the individual performing the surveys.

ITEM No. 18

Control No. 7 7 3 4 5

(4/82)