NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 8-31-87

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

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

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Beta Diagnostics, Inc.
7922 Ewing Halsell, Suite 100
San Antonio, TX 78229

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

(030-30536)

Refer to Item I attached

VLSL 26941

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Gordon L. Bilbrey, M.D. or Jeff Weix

TELEPHONE NUMBER: (512) 690-1548

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY: 7C

AMOUNT ENCLOSED: $ 580.00

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
G L Bilbrey	GORDON L. BILBREY, M.D.	RADIATION SAFETY OFFICER	4/11/88

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

- [ ] <$250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial–proprietary–information furnished to the agency in confidence)*

- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
App	Agr-3-IV	7C	8905080232 880726 REG4 LIC30 42-26941-01 PDC	M. Hunnin

AMOUNT RECEIVED	CHECK NUMBER	DATE
$580	3435	4/18/88

PRIVACY ACT STATEMENT ON THE REVERSE

Universal Consultants, Inc.

THIS CERTIFIES THAT

GORDON BILBRY, M.D.

HAS SUCCESSFULLY COMPLETED ALL REQUIREMENTS
FOR THE

COURSE ON BASIC RADIOISOTOPE HANDLING TECHNIQUES

AND AS PROOF OF PROFICIENCY IS HEREBY
AWARDED THIS

Certificate of Completion

ON THIS 27th DAY OF MARCH, 1984

Vincent A. Fasano

DIRECTOR OF TRAINING

LITHO IN U.S.A.

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ATTACHMENTS

I. NOTES

II. RADIATION DECAY OF I-125

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TRC Form 41-2a
(Rev. 10-82)

TEXAS DEPARTMENT OF HEALTH
APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
Human Uses

Instructions — Complete this application in accordance with the guide provided by the Texas Department of Health. Use supplemental sheets where necessary. Mail two copies to: Texas Department of Health, Bureau of Radiation Control, 1100 West 49th Street, Austin, Texas 78756. Upon approval of this application, the applicant will receive a Texas Radioactive Material License, issued in accordance with the provisions of the **Texas Regulations for Control of Radiation** (TRCR) and the **Texas Radiation Control Act.**

1. Name and Mailing Address of Applicant:

DAVID M. PLAYER, M.D.
SUITE 100
7540 LOUIS PASTEUR DR.
SAN ANTONIO, TEXAS 78229

2. Location(s) at Which Radioactive Material Will Be Used: (Street Address)

(refer to attached)

3. This Application is For:

☐ New License
☒ Amendment to present license # 9-3574
☐ Renewal of present license # _____

4. Location Where Records Will Be Kept:

same as Item # 1.

5. Using Physician(s):

Amend to add;
GORDON L. BILBREY, M.D.

6. Radiation Safety Officer:

Name: DAVID M. PLAYER, M.D.

Office Telephone No.: (512) 690-1515

7. Radioactive Material Data

(a) *Element and mass number (check groups desired)*	(b) *Chemical or physical form (Make and model number if sealed source)*	(c) *Maximum number of millicuries to be possessed*	(d) *Use of each form*
☐ Group I, TRCR Schedule 41-C	Radiopharmaceuticals	As needed	Uptake, dilution, and excretion studies
☐ Group II, TRCR Schedule 41-C	Radiopharmaceuticals	As needed	Imaging and/or tumor localization studies
☐ Group III, TRCR Schedule 41-C	Generators and kit preparations	Total generator activities not to exceed two curies unless justified	Preparation of radiopharmaceuticals

Additional Items Desired
(such as Xenon, check sources, therapy materials)

(a)	(b)	(c)	(d)

(Continue on a supplemental sheet)

8. Are the physicians listed under Item 5 licensed to dispense drugs in the practice of medicine in the State of Texas?	Yes	No
9. Have the physicians listed under Item 5 been certified by a medical certification board? (If the answer is "Yes", give the year of certification, the board from which certification was received and the specialty of certification for each physician certified.) 1970 Internal Medicine Year 1974 Board Nephrology Specialty _____ (For more than one physician, use a supplemental sheet.)	Yes	No

10. The Following Information Must Be Submitted On Additional Sheets.

A. *Facilities* — Describe labortory facilities, shielding, sinks, storage facility, fume hoods, etc. Include floor plan of the department including the air flow pattern.

B. *Radiation Safety Procedures* — The Radiation Safety Procedures that will be used must be submitted in duplicate. The procedures must include the appropriate items as listed in the licensing guide.

C. *Radiation Detection Instrumentation* — List make and model number of survey, measuring, monitoring, and imaging instruments. For survey instruments, include the sensitivity range, energy response range and types of detectors used with each. Also state how often and by whom survey instruments will be calibrated.

D. *Technicians* — Describe the training, testing and supervisory program to be given technicians to assure that radioactive material will be used safely.

E. *Administrative Procedures* — If the nuclear medicine physician will not normally be present when radioactive materials are administered and scans are performed, the applicant must submit two copies of the nuclear medicine physician's Administrative Procedures for conducting a nuclear medicine program at the facility in absentia. (See Appendix C of the Medical Guide concerning the content of those procedures.)

F. *Certification of Using Physicians* — Each physician listed in Item 5 must certify that he or she is familiar with and agrees to abide by the statements, representations and procedures being submitted with this application and any other correspondence that causes the license to be issued or amended.

11. Certificate

I certify that the information contained herein and attached hereto is true and correct to the best of my knowledge and belief. (If the applicant is an institution, the administrator should sign below.)

_____
Signature of Applicant or Certifying Official

GORDON L. BILBREY, M.D.
Typed or Printed Name

_____
Date

_____
Title/Position

TRC Form 41-2a
(Rev. 10-82)

Texas Department of Health
PRECEPTOR STATEMENT FOR LICENSE APPLICATION

The back of this page must be signed by the physician's nuclear medicine preceptor.

Name And Address of Applicant Physician	Inclusive Dates Training Received
GORDON BILBREY, M.D. 7540 LOUIS PASTEUR DR. SAN ANTONIO, TX 78229	MARCH 27, 28, 29, 1984

Clinical Training And Experience Of Physician Who Will Use Radioactive Material

Isotope	Type Of Study Or Therapy	Number of Cases Observed *	Number Of Cases Involving Active Participation **
	Uptake, Dilution, And Excretion Studies		
	Therapy Procedures		

(Continued on Page Four)

Isotope	Type Of Study Or Therapy	Number of Cases Observed *	Number Of Cases Involving Active Participation **
	Imaging And Tumor Localization Studies		
I-125	BONE DENSITOMETRY	FIVE	FIVE

* Observation should consist of observing radioisotope administration techniques and discussion with preceptor of case histories.

** Active participation should include (a) examination of the patient, (b) recommendation of dosage, (c) collaboration in the calibration and administration of the dose, and (d) followup of patient through treatment period.

TOTAL NUMBER OF HOURS OF PARTICIPATION IN CLINICAL TRAINING: EIGHT HOURS.
TOTAL NUMBER OF HOURS OF CLASSROOM AND LABORATORY TRAINING: TWELVE HOURS.

I CERTIFY THE ABOVE NAMED PHYSICIAN SUCCESSFULLY COMPLETED THE TRAINING AS SPECIFIED ABOVE.

STEVEN J. HARWOOD, M.D., PhD AT UNIV. OF FLORIDA

Name of physician (preceptor) Institution

Signature

TRC FORM 41-3
(10-78)

1302

TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

Pursuant to the Texas Radiation Control Act and Texas Department of Health regulations on radiation, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Texas Department of Health now or hereafter in effect and to any conditions specified below.

LICENSEE

1. Name: Beta Diagnostics, Inc.
dba/ Beta Osteoporosis Diagnostic Center

2. Address: ATTN: Gordon L. Bilbrey, M.D.
7922 Ewing Halsell, Suite 100
San Antonio, Texas 78229

This license issued pursuant to and in accordance with
☐ APPLICATION ☒ LETTER ☐ _____
Dated: November 15, 1986
Signed By: J. Weix, R.N.

3. License Number	Amendment Number
9-3574	9

PREVIOUS AMENDMENTS ARE VOID

4. Expiration Date: April 30, 1991

RADIOACTIVE MATERIAL AUTHORIZED

5. Radioisotope	6. Form of Material	7. Maximum Activity*	8. Authorized Use
A. I-125	A. Sealed sources (AECL C-235, C-324)	A. No single source to exceed 400 mCi. Total: 800 mCi.	A. One source for use in the Norland 2780 bone mineral analyzer for diagnosis of humans and the other for storage in its authorized shipping container during periods of source exchange.
B. Gd-153	B. Sealed sources (Norland N-1077)	B. No single source to exceed 1 Ci. Total: 2 Ci.	B. One source for use in the Norland 2600 bone mineral analyzer for diagnosis of humans and the other for storage in its authorized shipping container during periods of source exchange.

☐ CONTINUED ON PAGE 2, IF CHECKED.

CONDITIONS

9. Notwithstanding Texas Regulations for Control of Radiation 21.202, the licensee is hereby exempted from providing personnel monitoring equipment to the individuals using the radioactive material authorized by this license, except for persons who perform exchange of the radioactive source contained in the bone mineral analyzers.

10. Radioactive material shall be used only by the following:

Gordon L. Bilbrey, M.D.
David M. Player, M.D.
Cleve B. Collins, M.D.

* Ci-Curies mCi-Millicuries μ Ci-Microcuries

CONDITIONS CONTINUED ON PAGE 2.

TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

3886

LICENSE NUMBER	AMENDMENT NUMBER
9-3574	9

CONDITIONS CONTINUED:

11. Radioactive material may be used only at the following locations:

A. Site 000 - 7922 Ewing Halsell, Suite 100, San Antonio, Texas 78229.

Sub-site 001 - terminated

Sub-site 002 - terminated

Sub-site 003 - terminated

Sub-site 004 - terminated

Sub-site 005 - BMA Eagle Pass, 950 Puebla Drive,
Eagle Pass, Texas 78752

Sub-site 006 - terminated

Sub-site 007 - Laredo Kidney Clinic, 1020 Rear East Calton Road,
Laredo, Texas 78041

Sub-site 008 - terminated

Sub-site 009 - terminated

Sub-site 010 - terminated

Sub-site 011 - terminated

Sub-site 012 - terminated

Sub-site 013 - terminated

B. Physicians' offices and medical clinics throughout the State of Texas except those under exclusive Federal jurisdiction.

C. Hospitals, long-term care facilities and kidney dialysis facilities, licensed or exempted as such by the Texas Department of Health, except those under exclusive Federal jurisdiction.

CONDITIONS CONTINUED ON PAGE 3

TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

3887

LICENSE NUMBER	AMENDMENT NUMBER
9-3574	9

CONDITIONS CONTINUED:

12. Each use of bone mineral analyzer authorized by this license shall be ordered, supervised, and interpreted by the authorized users listed in Condition 10 of the license. Orders shall be maintained for inspection by the Agency at the address shown in Condition 11(A) above.

13. The individual designated to perform the functions of Radiation Safety Officer for activities covered by this license is Gordon L. Bilbrey, M.D.

14. The licensee shall maintain a utilizaton log for all bone mineral analyzer usage. This log shall include at least the following information:

    a. Date and time of use.

    b. Address of use including facility or physician's name.

    c. Patient's name.

    d. Name of ordering physician (an authorized user on this license).

    e. Name of technician, if applicable, operating the bone mineral analyzer.

    f. Identification of the specific bone mineral analyzer used.

15. No authorization in this license may be used as a basis for obtaining reciprocal recognition of this license by another Agreement State or the U.S. Nuclear Regulatory Commission.

16. The licensee shall not open or remove sealed sources containing radioactive material from their respective source holders.

17. Exchange of the radioactive source contained in the bone mineral analyzer shall be performed by persons who can provide documentation of satisfactory completion of the manufacture's approved radiation safety course.

18. Radioactive material which is transported by the licensee or delivered to a carrier for transport shall be packaged, labelled and transported in accordance with U.S. Department of Transportation Regulations.

CONDITIONS CONTINUED ON PAGE 4

TRC FORM 41-3a
(10-78)

TEXAS DEPARTMENT OF HEALTH
RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

3888

LICENSE NUMBER	AMENDMENT NUMBER
9-3574	9

CONDITIONS CONTINUED:

19. Except as specifically provided otherwise by this license, the licensee shall possess and use the radioactive material authorized by this license in accordance with statements, representations, and procedures contained in the following:

application dated September 2, 1986,
letter received September 25, 1986,
letters dated October 7, 1986, and November 15, 1986.

The Texas Regulations for Control of Radiation shall prevail over statements contained in the above documents unless such statements are more restrictive than the regulations.

MH:lk

Date January 24, 1987

FOR THE TEXAS DEPARTMENT OF HEALTH

Joseph G. Klinger

Administrator, Licensing Branch

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4. Security

5. Leak Testing

6. Personnel Monitoring

7. General Safety Rules

8. Emergency Procedures

9. Waste Management

C. Radiation Detection Instrumentation

D. Personnel Training Program

II. RADIOACTIVE MATERIALS

RADIOISOTOPE	CHEMICAL/PHYSICAL FORM	MAXIMUM ACTIVITY
Iodine-125	Sealed Sources (AECL C-235, C-234)	No single source to exceed 400 mCi

Authorized Use

For use in the Norland 2780 bone mineral analyzer for diagnosis of humans and storage in its authorized shipping container during periods of source exchange.

III. AUTHORIZED USERS

GORDON L. BIILBREY, M.D.

IV. ATTACHMENTS

I. AUTHORIZED PLACE OF USE

The licensed material may be used at health care facilities and physicians offices anywhere where the U.S. NRC maintains jurisdiction for regulating the use of licensed material and in Agreement States under reciprocity as long as the duration of use does not exceed 180 days in each state.

BETA DIAGNOSTICS, INCORPORATED

A. DESCRIPTION OF PROGRAM

1. Densitometry/absorptiometry units will be used by technologists under the supervision of Gordon L. Bilbrey, M.D.

2. The device will be used by technologists supplied by Beta Diagnostics, Inc. Devices will be used only at health care facilities that are not already licensed by the N.R.C.

3. The analyzers will be used to scan only patients that are referred for testing by a physician.

4. Prior to use, a letter will be obtained from the facility Administrator authorizing the analyzer use at such location.

5. Devices will be stored at the address of Beta Diagnostics, Inc. as stated in this application until such time as transfer is to take place for use at health care facilities.

6. Devices will be transported to the health care facilities by the technologists working under the supervision of Gordon L. Bilbrey, M.D. under approved D.O.T. regulations.

7. Prior to use, the device will be checked for proper operation in accordance with the attached procedures.

8. A transfer log will be maintained. The log will be kept on file at Beta Diagnostics, Inc. for review by the N.R.C. The log will contain the following items:

   a. Date of transfer of analyzer to the specific facility
   b. Address where the analyzer is to be used
   c. Serial Number of the analyzer utilized
   d. Technologist who utilized the analyzer
   e. Name of authorized user supervising use of analyzer
   f. Date of return of analyzer

9. Instruments and isotopes will be supplied by Beta Diagnostics, Inc. for use at health care facilities throughout the United States where the N.R.C. has jurisdiction.

10. Source exchanges will be performed by Beta Diagnostics, Inc.

11. The technologists will receive training as described in 10 CFR 19.11.

12. The device will be locked and secured against unauthorized removal at all times that it is not in use.

RECEIPT OF RADIOACTIVE SOURCE

FACILITY: _____

SOURCE SERIAL NUMBER: _____

SOURCE MODEL NUMBER: _____

1 Date source received: _____/_____/_____

2. Shipping carton: no damage_____ punctured_____ stained_____ wet_____ crushed_____

3. Shipping carton: White Label contents_____ Activity_____

4. Shipping carton: Hazardous Materials Label applied and completed_____

5. Measured radiation levels (survey meter):

   a. Shipping carton surface: _____ mR/hr

   b. 3 feet from surface: _____ mR/hr

6. Shipping carton opened and contents verified:

   a. Leak test certificate received_____ Date of leak test_____ (within last 6 months)

7. Radioactive source verified (I-125)_____ (Gd-153)_____ Nominal activity _____ mCi

8. Do the packing slip and the source agree as per line #7 above?: yes_____ no_____

   If they do not agree how are they different?: _____

   _____

   Beta Diagnostics notified: yes_____ no_____

9. Measured radiation levels (survey meter):

   a. Packing materials: _____ mR/hr

10. Source removed from container with hex head sealing bolt and cap in place_____

11. Cap removed and source secured in scanner assembly_____

12. Scanner key retained by Radiation Safety Officer_____

13. Shipping carton and container retained for future use_____

These safety checks have been performed and are in compliance with the provisions listed in the Radioactive Materials License.

RSO Signature_____ Technician Signature_____

Date_____

Beta Form RS100

RETURN OF RADIOACTIVE SOURCE

FACILITY:_____

SOURCE SERIAL NUMBER:_____

SOURCE MODEL NUMBER:_____

1) Radioactive source removed from scanner unit_____

2) Source capsule cap secured tightly_____

3) Shipping container re-examined for visual damage_____

4) Shipping carton re-examined for visual damage_____

5) Radioactive source placed into shipping container_____ lid secured_____

6) Shipping container placed into shipping carton_____

7) New radioactive white-1 labels applied to carton_____

8) mCi activity reduced to current level on white-1 label_____

9) Shipping label completed_____ Postal courier notified of pick-up_____

10) Radioactive source return notification completed and mailed_____

Courier Signature_____ Date of pick-up_____

These safety checks have been performed and are in compliance with the provisions listed in the Radioactive Materials License.

RSO Signature_____ Technician Signature_____

Date_____

7. WIPE RESULTS

a. Bkg _____CPM (Eff.= ____%) -> CPM x $\frac{100}{\text{eff.}}$ = _____bkg. DPM

b. Outer _____CPM (Eff.=____%) -> CPM x $\frac{100}{\text{eff.}}$ = _____ DPM

c. Final source container _____CPM (Eff.= ____%)

-> CPM X $\frac{100}{\text{eff.}}$ = _____DPM

8. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____mRem/hr, CPM

9. DISPOSITION OF PACKAGE AFTER INSPECTION_____

10. IF NRC/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE, AND PERSONS NOTIFIED.

_____

B. RADIATION SAFETY PROCEDURES

1. 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 pertinent to this 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.

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 transfers.

f. Assume proper completion and records of Department of Transportation (DOT) shipping papers and labelling of outgoing shipments or transfers.

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

h. Schedule and maintain any license/regulatory requirements such as the scheduling and maintenance of semi-annual leak test of sources, instrument calibrations, and maintenance of required records.

i. Maintain all other 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.

1. Continued

   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.

2. Ordering and Receiving Radioactive Materials

   a. Sources will be ordered only at the direction of the Radiation Safety Officer or authorized user.

   b. Sources will only be received during normal working hours and only by the Radiation Safety Officer, authorized user 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 3) and proper records maintained.

3. Procedures for Safely Opening Packages containing Radioactive Material (Initial receipt only)

   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 the regulations if removable contamination exceeds 0.01 uCi/100 cm sq. or if external radiation levels exceed 200 mR/hr at the package surface or 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 procedures and notify the Radiation Safety Officer.

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

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

3. Continued

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 GM survey meter, and take precautions against the spread of contamination as necessary.

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

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" (See next page).

4. Security

a. Storage:

All sources not locked in Bone Densitometer will be stored in a locked steel storage cabinet to be used only during periods associated with source exchange. The source is use if lock in the scanner. Keys will be controlled by the Radiation Safety Officer, authorized user or their designee.

5. Leak Testing Procedures

Each sealed source shall be tested for leakage at intervals not to exceed 6 months. In the absence of a certificate from a transfer or that a test has been made within the 6 months prior to the transfer, the sealed source shall not be put into use until tested.

The leak test shall be capable of detecting the presence of 0.005 microcuries of removable contamination on the sealed source. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the appropriate regulatory body for 2 years after the next required leak test is performed or until the sealed source is transferred or disposed of.

a. Follow any manufacturer instructions or specific license conditions for proper access and wipe testing of the sources.

b. Use time, distance, and shielding to reduce radiation exposure as low as reasonably achievable.

c. Use rubber gloves and remote handling devices in handling or working near radiation source containers, or when working with any potentially contaminated materials.

d. Wipe tests should only be performed by the licensed users or the Radiation Safety Officer.

Procedure

a. Place source behind shielding (if applicable) or check that direct radiation exposure is not possible.

b. Remove alcohol swab from packet to soak the "wet swab" cotton applicator.

c. Wipe all accessible surfaces with the wet swab (or nearest the source container, if applicable).

d. Place wet swab cotton applicator in plastic sleeve marked "WET SWAB" and seal open end. (Tape or staple)

e. Remove the "dry swab" cotton applicator and wipe all accessible surfaces of the source or container.

f. Place the "dry swab" cotton applicator in plastic sleeve marked "DRY SWAB" and seal open end.

g. Return source to storage (if applicable) or check that device is in proper safeguard mode.

5. Continued

h. Survey each swab with GM survey meter. If reading is above normal background, note this on back of kit and call Health Physics Services Inc., for further instructions.

i. Assuming the survey meter reading indicates no detectable activity, return the kit to the *address on the kit instruction in a standard size envelope.

j. The leak test certificate should be received within 2 weeks after the sample kit is received by the analyzing laboratory. If not, please call.

* Health Physics Services, Inc., Maryland Radioactive Material License No. MD-31-035-01

6. Monitoring of Personnel Exposures

All personnel involved in source transfer or routine used of the densitometer will, as a minimum, wear TLD ring badges (extremity monitors). These will be supplied by Health Physics Services, Inc., Rockville, Maryland, and will be exchanged on a monthly basis. These badges will be Landauer or Siemens film badges or other NVLAP approved badges.

7. General Rules for the Safe Use of the Densitometer

a. Wear personnel monitoring devices (TLD) at all times while working with radioactive material. TLD ring badge should be worn on dominant hand. Personnel monitoring devices should be stored in a designated low background area when not is use.

b. TLD finger badges will be worn during all source handling procedures.

c. Extremities of no one, except the patient, shall be placed in the primary beam.

d. Never remove sources from brass shielding capsules.

e. Wear disposable gloves at all times during source exchange.

f. 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.

7. Continued

g. Monitor hands and clothing for contamination after each procedure when sources are handled out of the Bone Densitometer.

h. 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.

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

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

8. Emergency Procedures

a. In the event of a radiation incident involving the rupture of the 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.

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: _____

Office Phone: _____

Home Phone: _____

Alternate(s)

Name: _____

Office Phone: _____

Home Phone: _____

9. Waste Management

Clinics will return used sources in their brass shields, packaged in accordance with applicable DOT and State regulations to the manufacturer for disposal.

C. RADIATION DETECTION INSTRUMENTATION

1. Instrumentation

   Radiation Survey Meter

   A low range survey meter will be available (0-50 mR/hr)

2. Calibration of Instruments

   Calibration of Survey Instruments

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

   b. Survey instruments will be calibrated by Health Physics Services, Inc., Rockville, Maryland under License No. MD-31-035-01.

   c. Procedures and sources have been approved by the State of Maryland, License No. MD-31-035-01 and follows the procedures of Appendix , U.S.N.R.C. Regulatory Guide 10.8.

   d. The following are the approved procedures used by Health Physics Services, Inc.

      1. 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

         a. Turn on instrument to be calibrated and check batteries, etc. Replace as necessary.

         b. Prepare calibration certificate in duplicate.

         c. Unlock calibrator and remove source plug.

         d. Compare instrument at two points on each scale (approximately 30% and 70% of scale), to known exposure exceeds ±10%, make appropriate adjustments in accordance with the instrument manual.

e. After appropriate adjustments, repeat Item 4 above. If deviations still exceed ±10%, forward for appropriate maintenance with customer's consent.

f. Complete calibration certificate and insure that true exposure and meter response is listed for two or more points on each scale.

g. Replace plug, lock calibrator, and sign certificate.

h. Insure that certificate accompanies instrument when returned to customer.

i. 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.

D. PERSONNEL TRAINING PROGRAM

Personnel Training Program

All personnel whose duties may required them to work with the radioactive material will be informed about radiation hazards and appropriate precautions.

Personnel will be properly instructed:

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

2. During annual refresher training.

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

Instruction will include:

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

2. Potential hazards associated with radioactive material.

3. Radiological safety procedures appropriate to their respective duties.

4. Rules and regulations of the license.

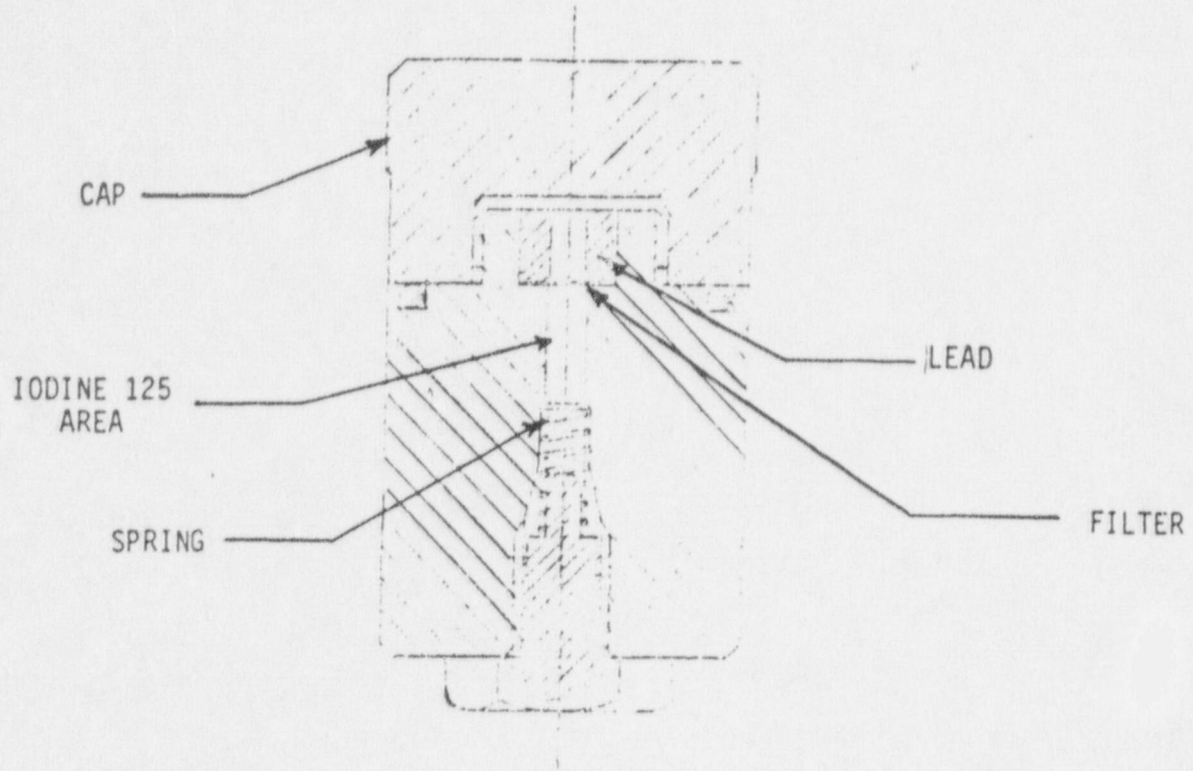
5. Obligation to report unsafe conditions to the Radiation Safety Officer.

6. Appropriate response to emergencies or unsafe conditions.

7. Right to be informed to their radiation exposure and bioassay results.

8. 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).

FIGURE #1



About The Bone Densitometer

The Bone Densitometer makes its measurements by passing the photon beam from the Iodine-125 source through a bone and measuring the intensity of the resulting beam compared to the raw beam which is not passed through the bone. The ratio of attenuated to non-attenuated beam intensities measures the amount of bone mineral in the beam path.

When the source is installed in the Bone Densitometer scanner, its cap is removed and it is screwed into the shutter assembly. The shutter is an electrically-operated shield which covers the window in the source holder, preventing the radiation beam from getting out. The shutter assembly also provides collimation of the beam; that is, it narrows the beam into a thin pencil of radiation. The scanner is designed so that this beam is completely absorbed by the lower surface of the scanner head.

The shutter is opened only when a measurement or calibration is being done. At all other times it is closed and no radiation emerges from the scanner deck. When power is turned off, the shutter closes and remains closed.

PROCEDURES FOR CHANGING THE I-125 RADIOACTIVE SOURCE 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).

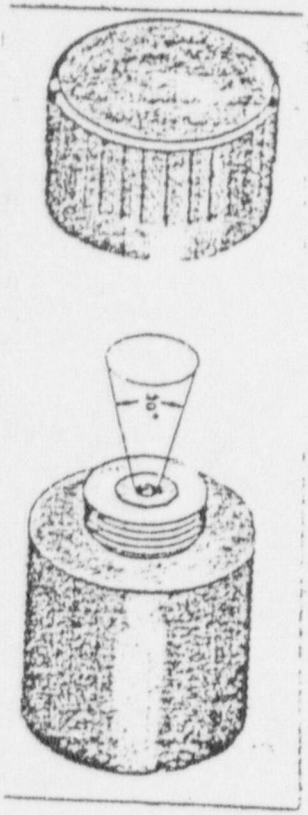


FIG. 1

"Source Assembly AECL C-236 or 178A591A with shipping cap removed 30 degree radiation field illustrated."

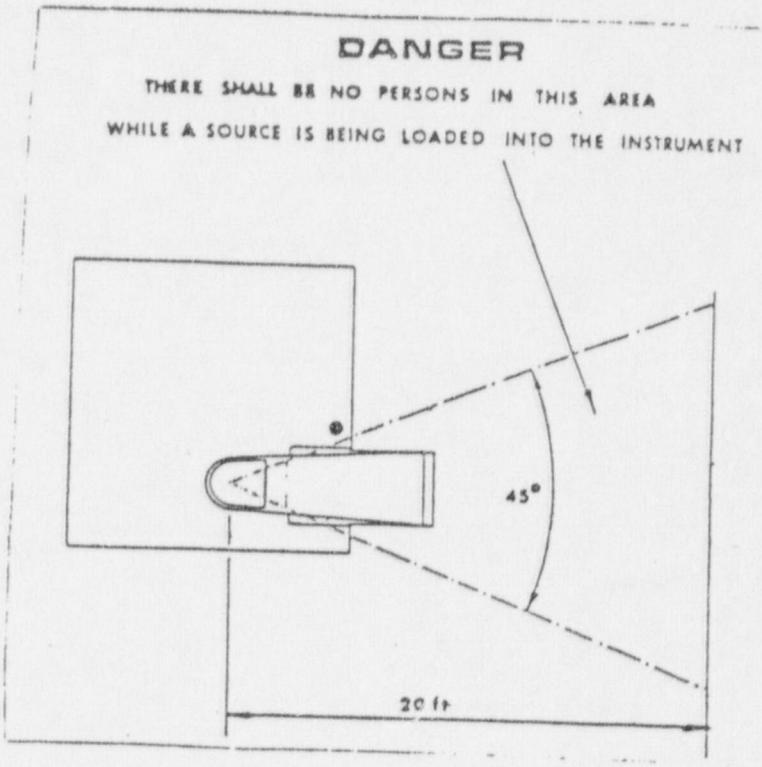


FIG. 2

"Radiation Hazard area during source loading and unloading."

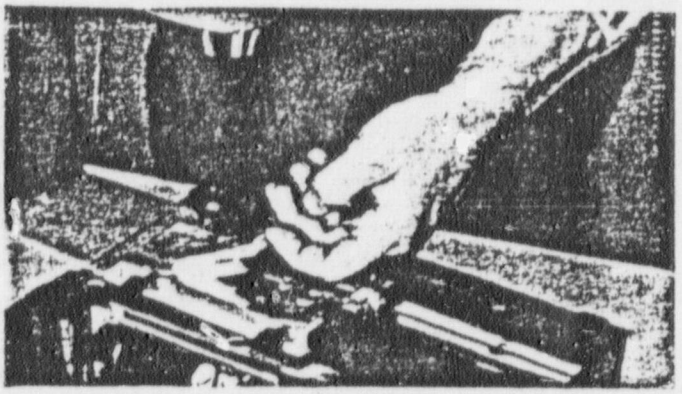
A 200 mCi source delivers a maximum dose rate of approximately 200 mr/min at a distance of 2.5 cm. The protective cover should not be removed until the source is actually installed in the scanner. When installing the source, be sure that there are no persons in the scanner area indicated by Figure 2.

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 deck is free.

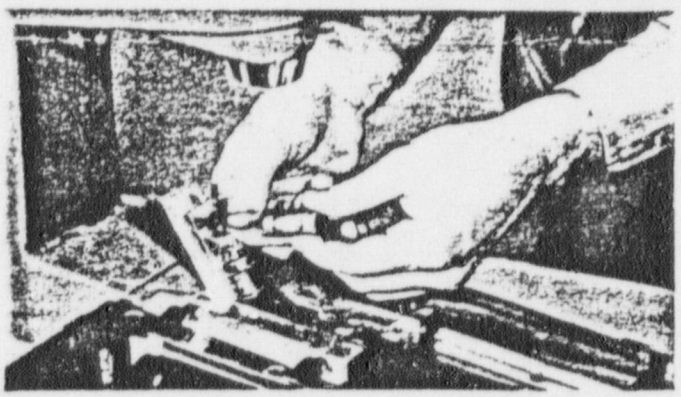
While loading or unloading the source, keep fingers away from the exposed end of the source holder at all times. Do not point the exposed source toward anyone. When removing the source from the scanner, reverse the loading procedure. Be sure to replace the cap on the source holder before tranporting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

PROCEDURE FOR LOADING SOURCE

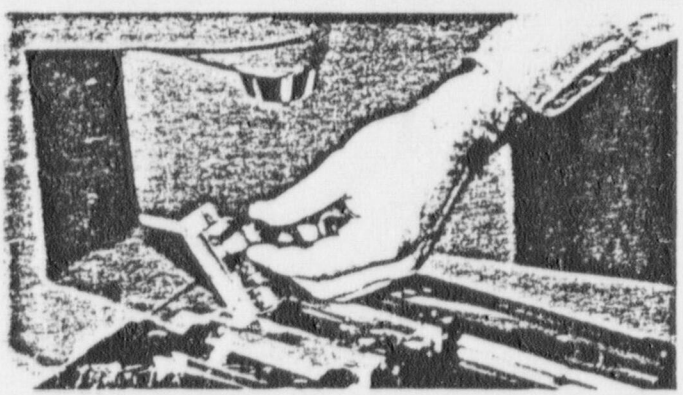
A. Lift source/shutter door.



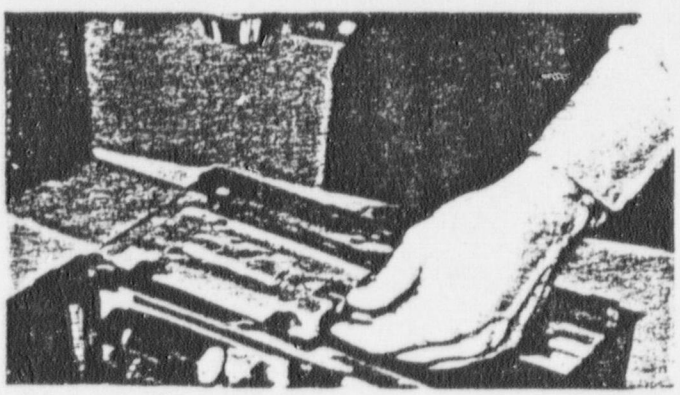
B. Remove source cap. Hold source in position shown.



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



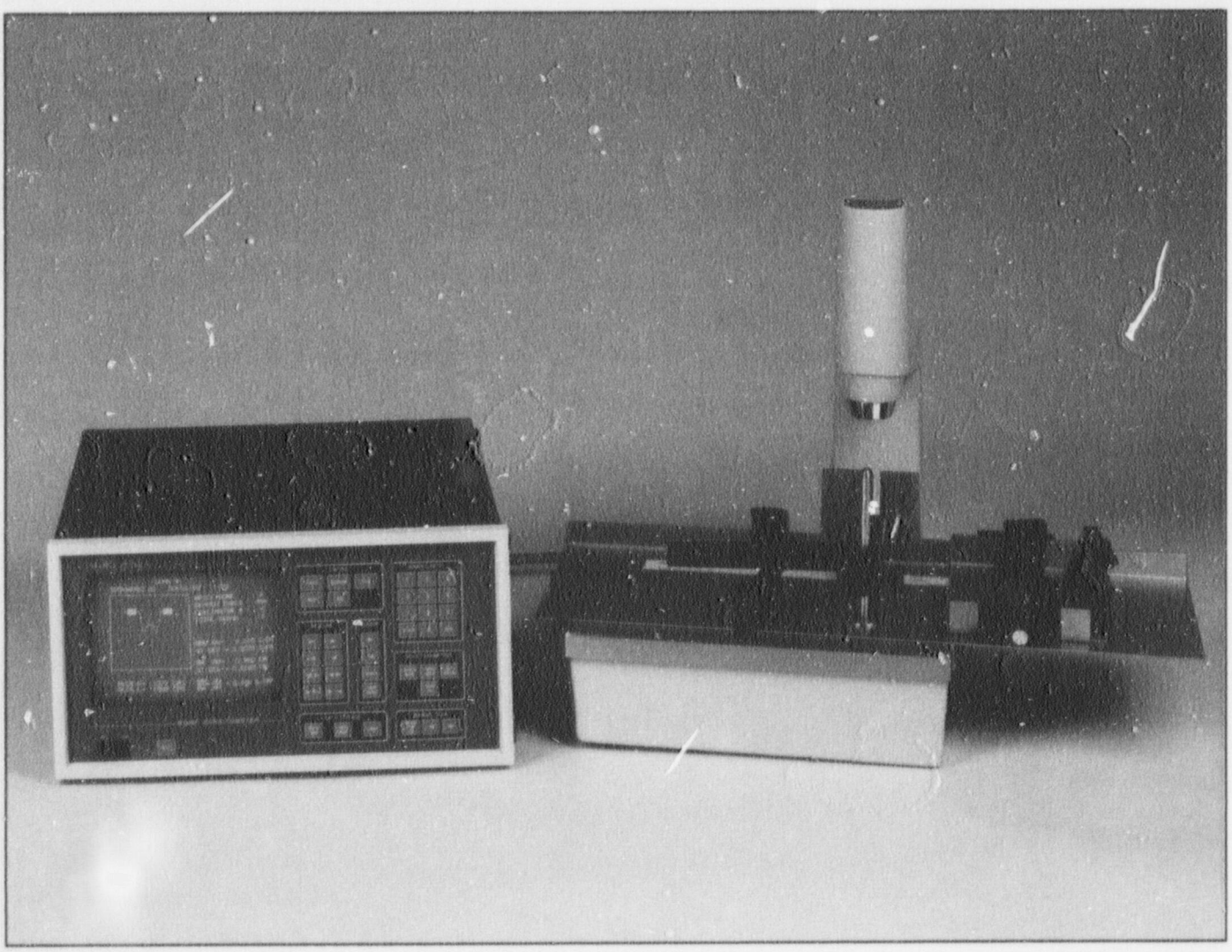
D. Store cap for later use on clip in scanner.



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

THE NORLAND MODEL 2780 SINGLE PHOTON BONE DENSITOMETER

A SIGNIFICANT ADVANCE IN BONE QUANTIFICATION



BONE QUANTIFICATION

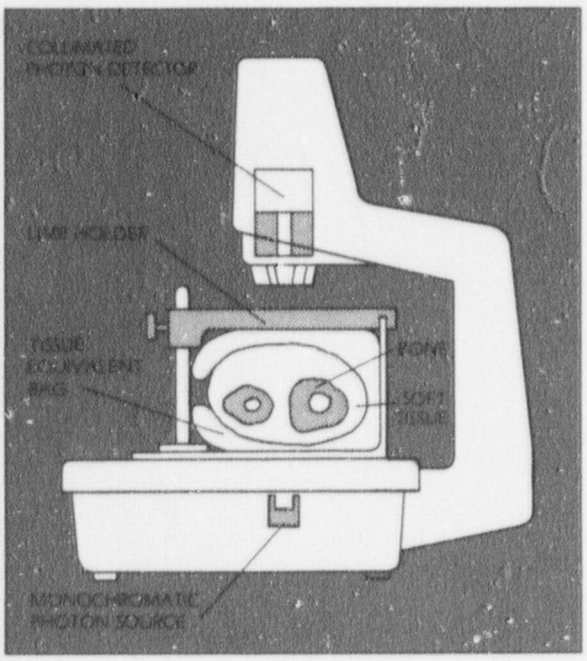
A NEED — A SOLUTION

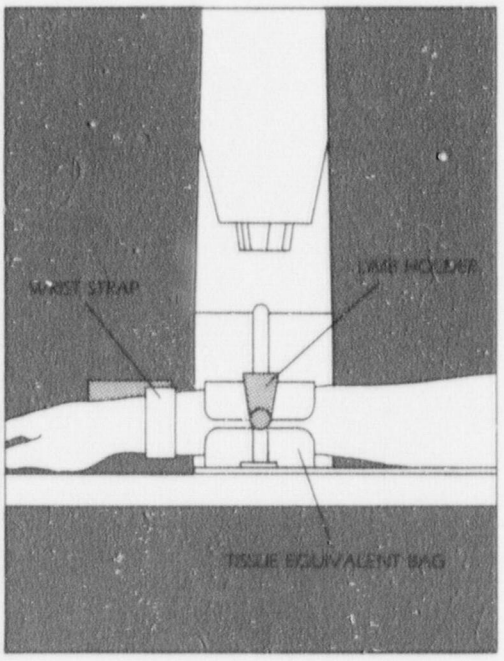
Physicians and clinicians have long recognized the shortcomings of biopsy or radiographic methods for the early detection of bone disease. In 1963, Cameron and Sorenson reported a new in vivo, non-intrusive method for quantifying bone mineral content — the photon absorption technique.[1] Since then,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

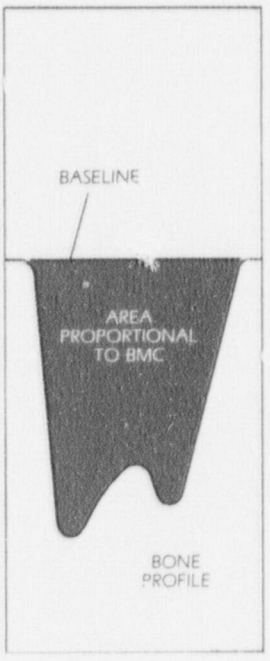
THE PHOTON ABSORPTION TECHNIQUE

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 DENSITOMETER



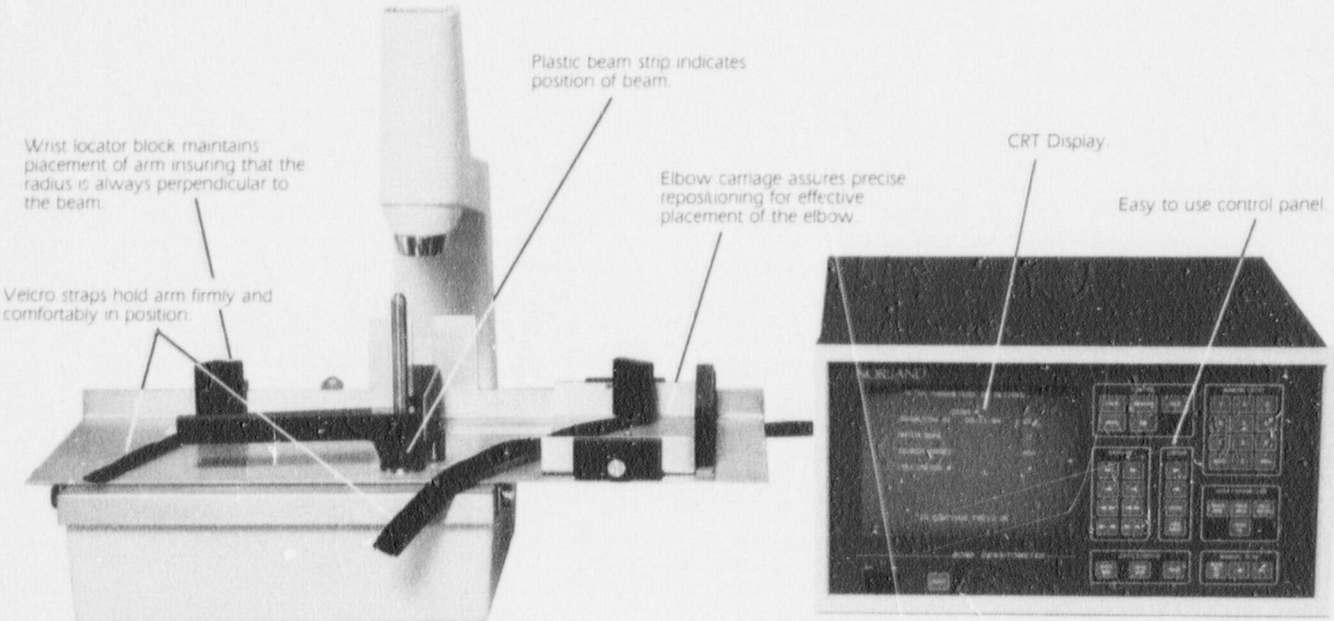




This proven instrument makes the advantages of the photon absorption technique available to you in a simple 15 minute procedure. Without causing patient discomfort, the Bone Densitometer measures bone mineral content as a linear density in grams per centimeter and bone width in centimeters. When measuring 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.

HOW THE SYSTEM WORKS

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



RELIABLE LIMB POSITIONING SYSTEM

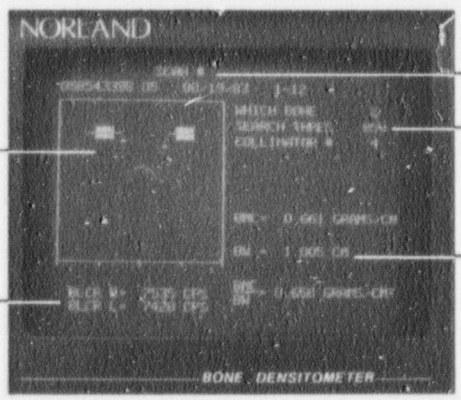
- The limb positioning system places the radius perpendicular to the beam and provides a firm stop for the end of the ulna at the flexed elbow.
- The forearm is held firmly but comfortably and enables precise positioning of scan sites.

EASY TO USE COMPUTER MODULE

- After power turn-on, the computer performs a rapid and extensive self-check.
- Calibration is a simple five minute procedure which need be done only once every two weeks.
- Multiple scans can be performed with the Bone Densitometer.

COMPLETE DISPLAY OF BONE MEASUREMENT INFORMATION

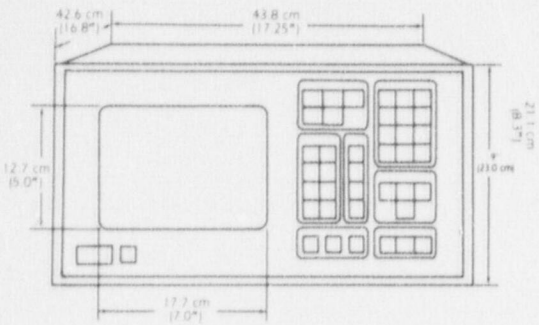
All information about a scan is presented on a large, bright CRT display:



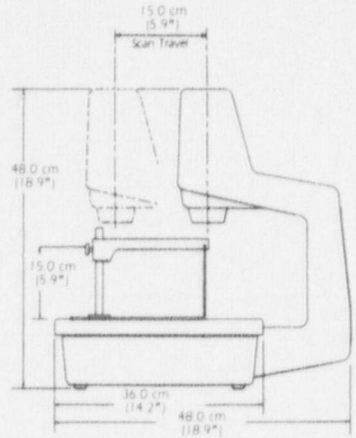
- scan number: 9-digit patient I.D., date, sequence number, and disk number.
- graphic results: bone profile showing individual data points, selected baseline, and bone edges.
- scan parameters: which bone, edge threshold, collimator.
- numeric results: BMC (bone mineral content), BW (bone width), and BMC/BW.
- baseline count rate through soft tissue surrounding bone.

THE NORLAND DIGITAL BONE DENSITOMETER

PHYSICAL SPECIFICATIONS



Computer Module Dimensions:
21.1 cm (8.3")H x 43.8 cm (17.25")W
x 42.6 cm (16.8")D
19.8 kg (43.6 lb.)



Scanner Module Dimensions (arm retracted):
48.0 cm (18.9")W x 36.0 cm (14.2")D
x 48.0 cm (18.9")H
18 kg (39.6 lb.)

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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Specifications subject to change without notice.

A recognized leader in technology and electronic instrumentation, Norland has been designing and building superior Bone Densitometry systems since 1970. We are dedicated to continuing this commitment to leadership and service. For more information on Norland Corporation or our products, contact us directly or call your local Norland representative. We respond promptly.

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Norland Scientific Instruments B.V.
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- **Interosseous Space Software**

The standard measurement site in the distal radius is the point at which the gap between the radius and ulna (interosseous space) is 5mm. It has been shown that measurements at this site monitor changes in the trabecular compartment. By measuring both the bone width and the interosseous space, the 2780's IOS software allows accurate and precise identification of scan site and has proven to increase efficiency and reduce subjectivity.

- **Optional Scanning Positioning Systems**

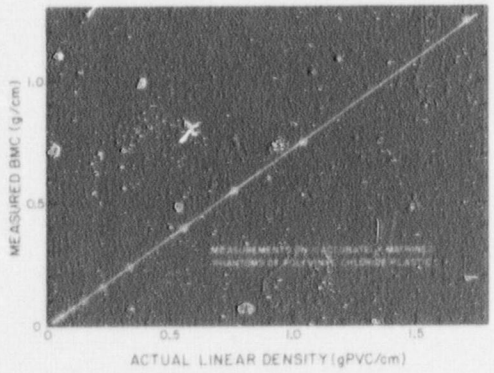
Optional scanning positioning systems are available to adapt the Bone Densitometer for measurement of finger bones, infant subjects and various animals.

- 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.

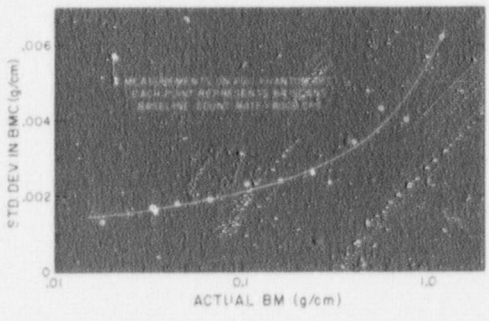


Linearity in Bone Mineral Content

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.

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]