

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.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20545

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY 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
NUCLEAR MATERIALS SAFETY 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
NUCLEAR MATERIALS SAFETY 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):

- ☒ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER _____
☐ C. RENEWAL OF LICENSE NUMBER _____

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

OB/GYN Associates
Suite 206
7605 Forest Ave.
Richmond, VA 23229

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

Same as Item 2.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Lawrence G. Miller, M. D.

TELEPHONE NUMBER

(804) 285-7802

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 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: 8707100078 870316
REG2 LIC30
45-24894-01 PDR

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT.

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

FEE CATEGORY 7.C. AMOUNT ENCLOSURE \$ \$580

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

Lawrence G. Miller M.D. Treasure

2/23/87

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

<\$250K	\$1M-3.5M
\$250K-500K	\$3.5M-7M
\$500K-750K	\$7M-10M
\$750K-1M	>\$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

AMOUNT RECEIVED

CHECK NUMBER

DATE

\$580

102638

251460

3/4/87

Henrico District Hospital

Item 5.

RADIOACTIVE MATERIAL

Gadolinium-153	Sealed Source	Source Model N-1077 (Gulf Nuclear Model GD-1, A/S GDC.CY1, NEN NER-430 or 431, Biosources OS-213A)
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Item 6.

PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED

Quantification of bone mineral content in-vivo.

Item 7.

TRAINING AND EXPERIENCE

Dr. Miller is completing an 8 hour course in basic radiation physics and instrumentation, radiation biology and radiation protection consistent with the policy and guidance directive EC 85-1 for licensing the Lixiscope and bone mineral analyzer, dated January 25, 1985 from Richard E. Cunningham, Director, Division of Fuel Cycle and Material Safety. This eight hour course is being presented to these physicians by Dean W. Broga, Ph.D.

Doctor Broga has had extensive experience in the safe use of radiation devices and radioactive materials. Dr. Broga is certified by the American Board of Health Physics. A letter of completion of the training will be forth coming from Dr. Broga.

Item 8.

PERSONNEL TRAINING PROGRAM

The bone mineral analyzer systems will be operated by or under the direct supervision of Dr. Miller. All other personnel within the facilities and all new employees will be instructed with regard to the presence of radiation source and the associated controlled area by authorized users and or the designated radiation safety officer. Instruction and information will be provided consistent with 10CFR19. Complete instructions in the safe use and handling of the Gd-153 source and operation of the instrument will be provided by the Norland Corporation at the time of installation. This material will be used for future training.

Item 9.

FACILITIES AND EQUIPMENT

The Norland Model 2600A bone mineral analyzer will be installed at the following (see attached diagram).

OB/GYN Associates
Suite 206
7605 Forest Ave.
Richmond, Virginia 23229

The Norland system consists of two main modules, the table assembly on which the patient is scanned and the console assembly from which the scan is controlled by the operator. The table assembly contains the gadolinium-153 radionuclide source which emits 44 and 100 keV photons. The source is locked into the table assembly and shielded by a lead shutter (see attached diagram). The source beam is normally occluded by the lead shutter and is automatically exposed during scanning. Additional descriptive information regarding this equipment including diagrams are attached.

Radiation survey equipment is available to the OB/GYN Associates through Henrico Doctors' Hospital which is directly adjacent to the office building in which OB/GYN Associates is located. Equipment includes:

<u>Manufacturer</u>	<u>Model</u>	<u>Detector Type</u>	<u>Ranges</u>
Eberline	E-530	GM	0 - 250,000 cpm
			0 - 25,000 cpm
			0 - 2,500 cpm
			0 - 250 cpm
			0 - 200 mR/hr
			0 - 20 mR/hr
			0 - 2.0 mR/hr
			0 - 0.2 mR/hr
Victoreen	740-F	Ion Chamber	0 - 25,000 mR/hr
			0 - 2,500 mR/hr
			0 - 250 mR/hr
			0 - 25 mR/hr

Survey instruments are calibrated annually using Cs-137 specially designed for such calibration work. Source and calibration procedures are described in NRC License #45-00048-17 granted to Virginia Commonwealth University, Richmond, Virginia.

In addition, sealed source leak tests will be performed every six months by the above consultant using scintillation and/or gas flow detector systems with energy windowing capabilities. These detector systems have minimum detectable activity capabilities of less than 0.005 microcuries (uCi). The manufactures instructions will be followed during leak testing.

Item 10.

**RADIATION SAFETY PROGRAM
PROCEDURES AND PRECAUTIONS FOR USE OF
RADIOACTIVE MATERIAL**

Except during servicing and source leak testing the source will be locked within the bone mineral analyzer table unit. The area where the bone mineral analyzer is used will be locked whenever authorized personnel are not present.

Sources will be installed and/or exchanged in a manner consistent with the manufactures procedures. Sources will be installed and/or exchanged as a source/source holder combination. Such procedures will be performed by authorized Norland Corporations service personnel, the RSO and/or medical physics consultant, Dr. Dean W. Broga. Personnel monitoring will be used during such procedures.

The source will remain in the analyzer during servicing. The bone densitometer will be maintained by the Norland Corporation Service Department or by a person trained by Norland Corporation to maintain the 2600 system.

Sources will be returned to the supplier for disposal. Packaging will be in accordance with 10CFR71.

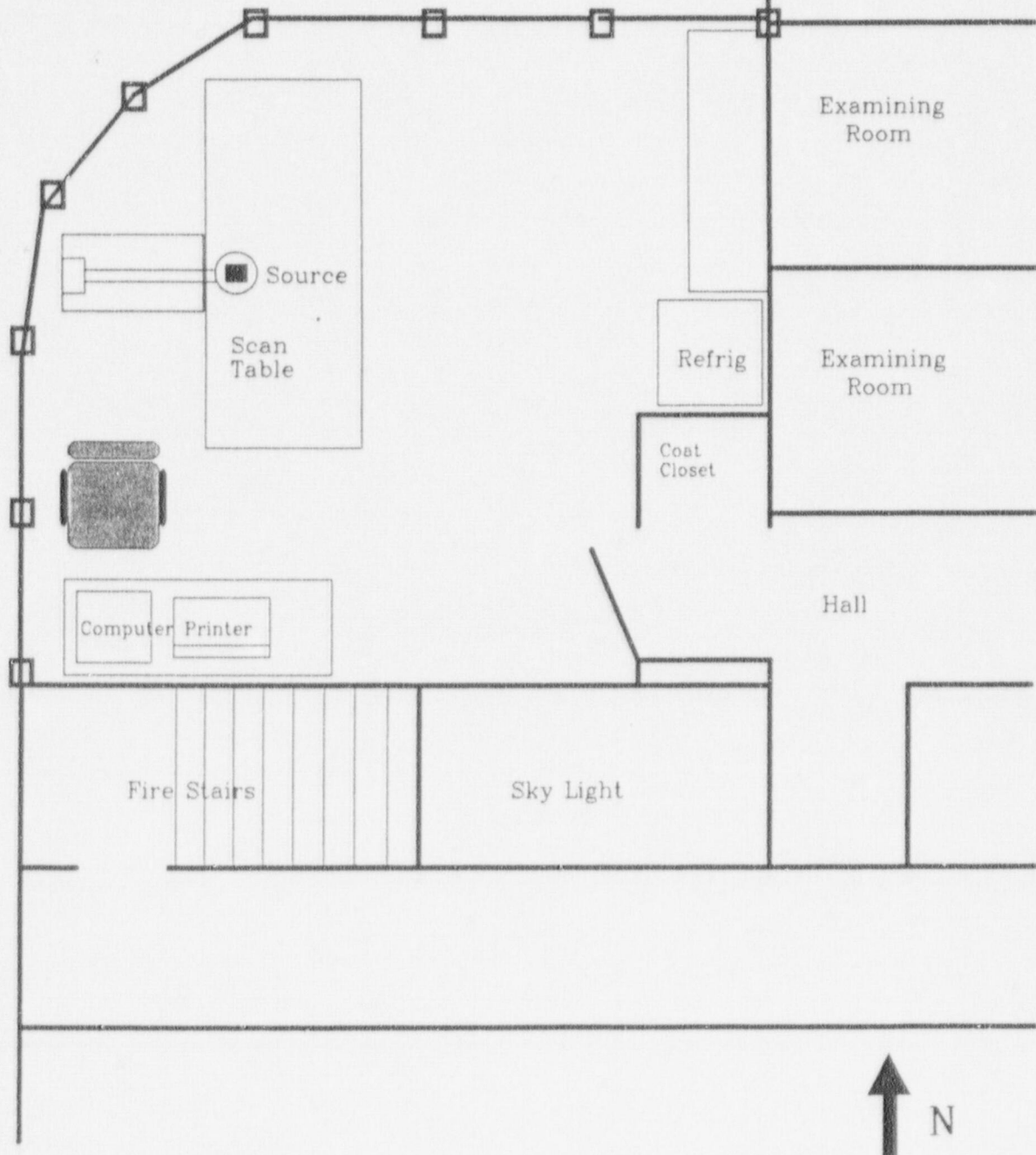
Radioactive materials (sources) will be ordered by the Radiation Safety Officer. The RSO will track and be conscious of expected delivery dates so that shipments can be quickly inspected. Delivery to the facilities will be specified for normal working hours and to the attention of the RSO. The RSO will insure that packages containing byproduct material are properly inspected within three hours after receipt during normal working hours.

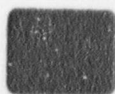
Item 11.

WASTE DISPOSAL

No actual disposal of waste will be performed. Expended sealed sources or sources determined to be unsatisfactory for safe and proper use in the designated equipment will be returned to the original manufacture as part of their source exchange program. Packaging will be in accordance with 10CFR71.

OB/GYN Associates
Suite 206
7605 Forest Ave.
Richmond, Virginia





The Norland 2600 Dichromatic Bone Densitometer

Specifications

Scanner:	
Mechanical	Active Scan Area: 185 cm by 55 cm Drive System: Gearhead stepper motors, Kevlar-reinforced timing belts, speeds from 0.1 to 30.0 mm per second, scanning at any angle (in any direction)
Source	Gadolinium-153, 1 Curie sealed source
Radiation Dose	0.007 mr/hr for operator, 3.2 mr/hr for patient
Photon Handling	Beam Diameter: 3.2mm (.125") at tabletop Tabletop-to-detector distance: 35cm (14") Detector Collimator: Two 8mm (.32") lead plate apertures separated by 5cm (2")
Patient Positioning System	Laser Beam Indicator: Safe (1 mW) positioning aid Leg Support: 3-position removable support block elevates lower legs so that lumbar spine is flattened for optimal vertebral separation
Physical Specifications	Tabletop Size: 243cm (96") by 76cm (30") Wall Clearance: 86cm (34") Power Required: 120 Volts at 1.5 Amps or 240 Volts at 0.5 Amps, 50 or 60 Hz Operating Temp: 15-40°C (60-105°F) Humidity: Up to 80% non-condensing
Control/Analysis Unit:	
Computer System	Computer: IBM Personal Computer AT with 640 KByte RAM memory, 20 MByte (50 MByte optional) hard disk, and 1.2 MByte floppy disk OR: IBM Personal Computer XT with 640 KByte RAM memory, 10 MByte hard disk, and 320 KByte floppy disk Display: IBM Color Display with 16 color Tecmar Graphic Master display package (640 by 200 pixel resolution) Printer: EPSON JX-80 color printer with Microfazer universal print buffer
Software	Analysis Software: Norland BoneStar Analysis software, resident on Hard Disk; updates supplied on floppy diskettes; operates under PC-DOS Multi-processing: Data review, analysis, printing, etc., can be done concurrently with patient scanning
Physical Specifications	Computer Desk Surface Size: 121cm (48") by 76cm (30") Wall Clearance: 13cm (5") Power Required: 120 Volts at 6 Amps, 50 or 60 Hz (N1151 Autotransformer option for 220 Volt operation) Operating Temp: 15-40°C (60-105°F) Humidity: Up to 80% non-condensing

Spatial Resolution: Line Spacing and Pixel (Point) Resolution within a scan line: 0.1mm to 10.0cm in 0.1mm increments

Scan Time: Less than 20 minutes for the following typical spine scan covering all of L2, L3, and L4, and portions of L1 and L5 using Scan Speed of 5mm/sec, Scan Line Length of 13cm, Vertical Extent Area of 13cm, Scan Line Spacing of 4mm, and Point Resolution within scan line of 2mm.

Printouts: A partial list of printed reports includes: Vertebral Analysis Results, Region Analysis Results, Patient Personal Data, Master Patient Directory, Patient Data Directory, and Calibration Log.

Calibration: Calibration of the system is done by scanning a special Calibration Phantom which is supplied with each instrument. A calibration log is automatically kept on disk and may be reviewed at any time.

Installation and Training: Complete on-site installation and comprehensive personnel training are included.

Warranty and Service: One year parts and labor from date of installation, plus we offer service contracts.

Government Agency Recognition:

Food and Drug Administration Number: K841463
Nuclear Regulatory Commission Certificates of Registration:
Model 2600 Bone Densitometer: NR-482-D-103-S
Model 1077-series Gd-153 Source Holder: NR-482-S-104-S

Currently approved isotope vendors:

Amersham Corp.	Model GDC.CY1
Biosources	Model OS-213A
Gulf Nuclear, Inc.	Model GD-1
NEN-Dupont	Model NER-430

Minimum Recommended Work Area Dimensions:

Scanner Unit:

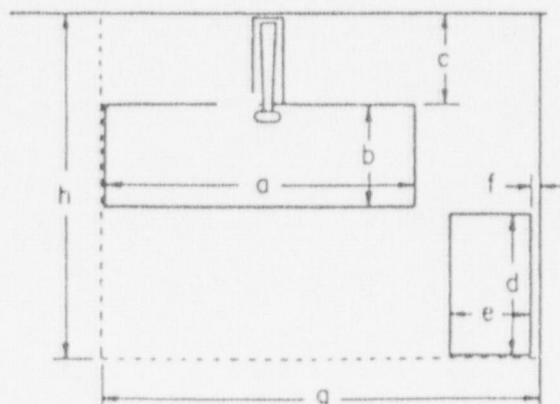
a Length	243cm (96")
b Width	76cm (30")
c Minimum Distance from Wall	86cm (34")

Control/Analysis Unit:

d Length	121cm (48")
e Width	76cm (30")
f Minimum Distance from Wall	13cm (5")

Total Work Area:

g Length	400cm (157")
h Width	285cm (112")



NORLAND MODEL 2600 DICHROMATIC BONE DENSITOMETERRADIATION DOSE INFORMATION

The radiation produced by this instrument, although highly localized and of low energy, is quite intense in the primary beam path, and should be regarded with due respect.

The dose rate at the surface of the scanner tabletop with a new 1 Curie source of Gadolinium-153 is approximately 4 millirads/sec. The beam is about 4 mm in diameter at the tabletop and widens to about 48 mm at the detector. The beam is completely absorbed by the detector head assembly.

The radiation is present only during a patient or calibration scan. When no scan is being done, an electrically operated shutter blocks the beam.

PATIENT DOSE

The radiation dose given to a patient being scanned is dependent on two factors: (1) the intensity (dose rate) of the radiation being emitted by the source, and (2) the time that each individual bit of tissue is exposed to the radiation. For example, if the intensity of the beam is 1 mr/sec, and the scan speed is 5 mm/sec, then the 5 mm diameter beam will pass over a point in the tissue in 1 sec., giving that point a dose of 1 mr. This is true of every point in the scanned area, so that the dose is 1 mr.

In the Model 2600 D.B.D., the scan speed is selectable by the operator, so that allowances may be made for decreasing source activity with time, variations in patient girth, and different precision requirements. The table below gives the patient dose for scans done at various speeds and using sources of various ages. A typical scan speed with a new source is 5 mm/sec.

		SOURCE AGE			
		New	6 mos.	12 mos.	16 mos.
SCAN	5 mm/sec	3.2 mr	1.9 mr	1.2 mr	0.7 mr
SPEED	2 mm/sec	8.0	4.7	2.9	1.7
	1 mm/sec	16.0	9.4	5.8	3.4

It may be questioned whether these doses are harmful to the patient. All radiation is harmful to some extent, but for the small doses delivered by diagnostic tools such as this instrument, the benefits usually outweigh the risks.

For comparison, a lumbar spine x-ray delivers a dose of from 1000 to 2000 mr.

OPERATOR DOSE

The manufacturing process used to make Gadolinium-153 entails the production

1. POWER ON

The operation of the DBD is described by example. The operator will begin by correcting the date and time setting of the real time clock in the computer. Next the operator will select an imaginary patient file and analyze scan information associated with that patient. Finally, a scanning operation and file storage operations will be done.

Turn on the computer CRT by turning the 1 \longleftrightarrow 0 knob to the 1 position. Next turn on the computer by pressing the 1/0 switch on the right side of the computer to the 1 position.

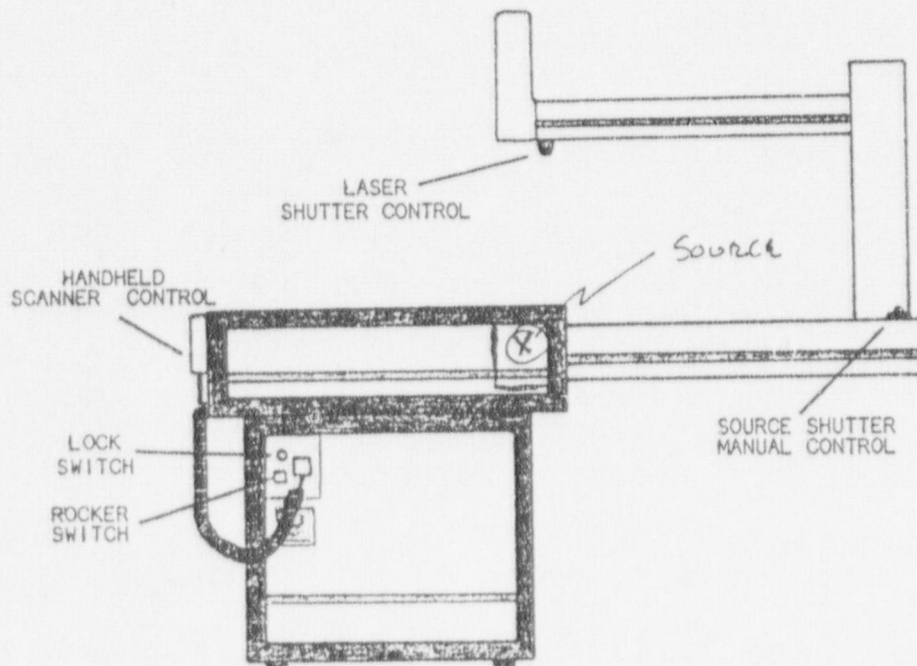


Figure 1 - Locations of scanner shutter control, lock switch and rocker switch

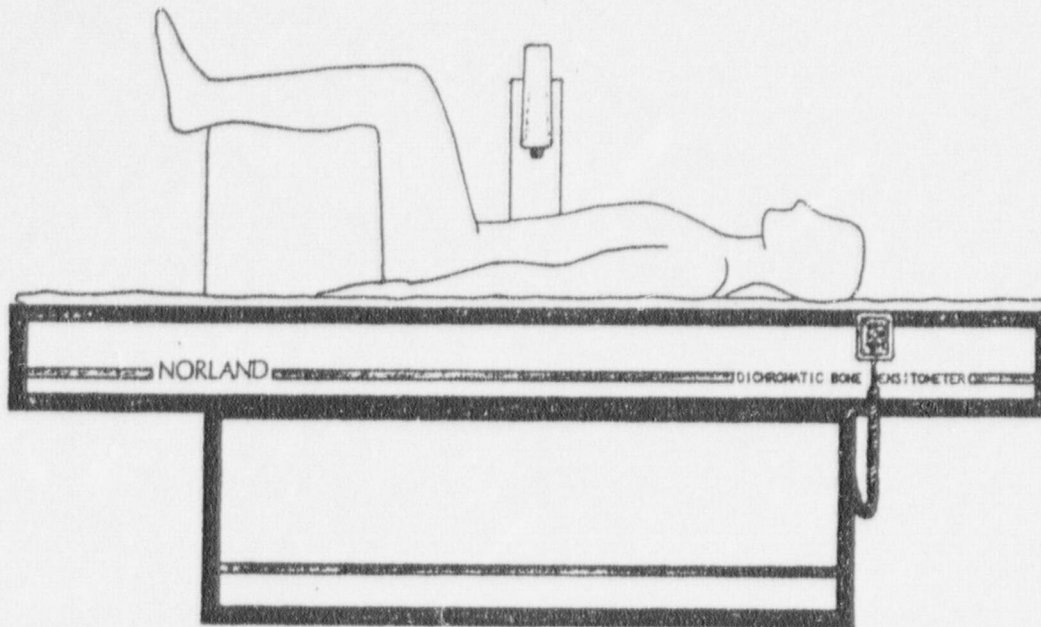


Figure 14 - Patient in position on scanner table with leg rest shown in place.

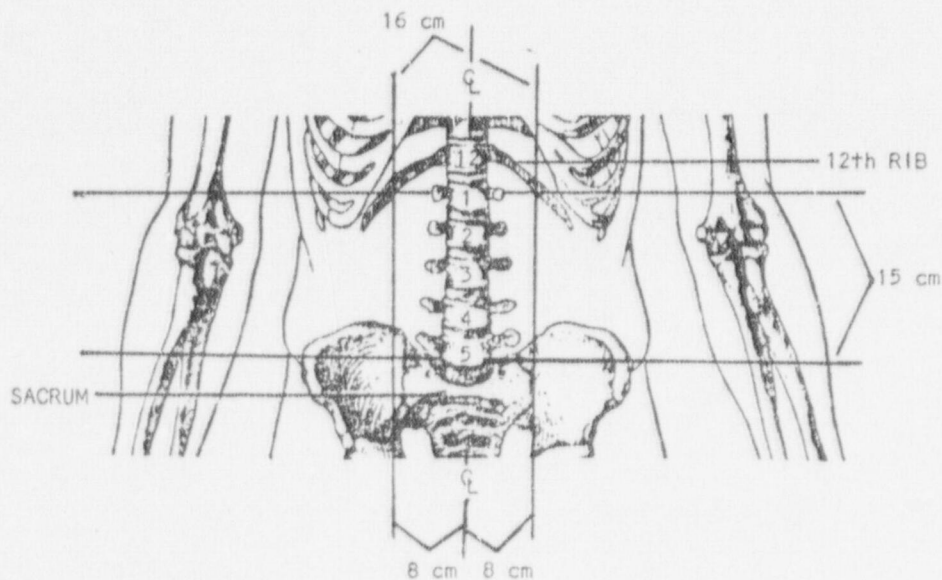


Figure 15 - Recommended scan area which will include all of the second, third, and fourth lumbar vertebrae.

13. INSTALLATION OF THE SOURCE

To install or change the DBD's radioactive source, begin by lifting off the scanner table's top panel. This will provide access to the source holder chamber.

Loosen the retainer clamp of the source holder chamber and rotate it out of the way. See Figure 26.

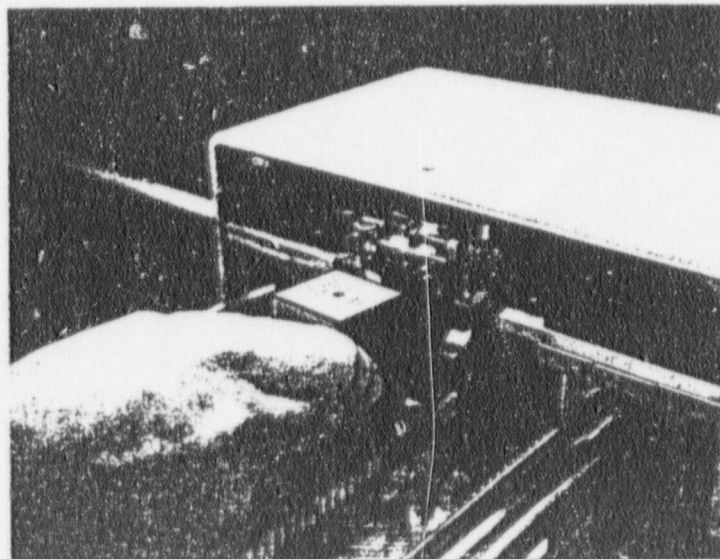


Figure 26 - View showing a loaded source holder about to be inserted into the source holder chamber. Note that the retainer has been rotated out of the way.

Position the loaded source holder to slide it into the chamber. Note that the arrow on the top of the source holder should be pointed toward the chamber. See Figure 27. Slide the source holder into the chamber. See Figure 28.

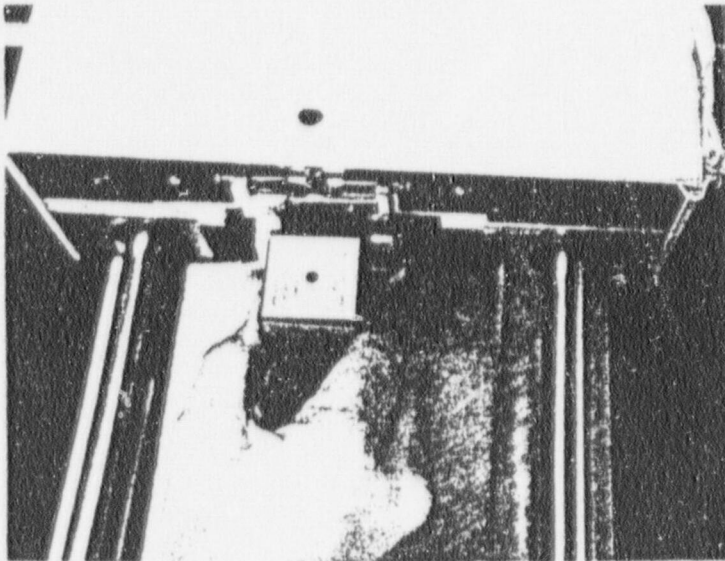


Figure 27

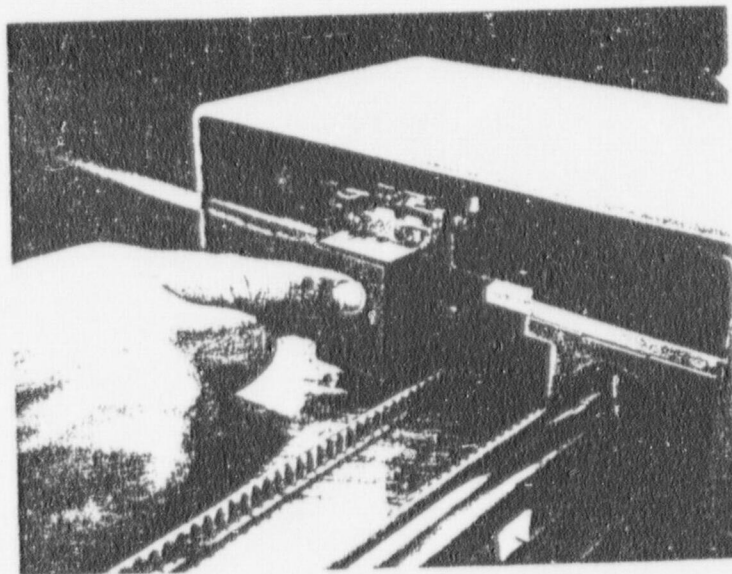


Figure 28

Once the source holder is pushed into the chamber as far as it can go, rotate the retainer clamp into position over the top edge of the source holder and tighten in place. See Figure 29.

To change sources, reverse the procedure.

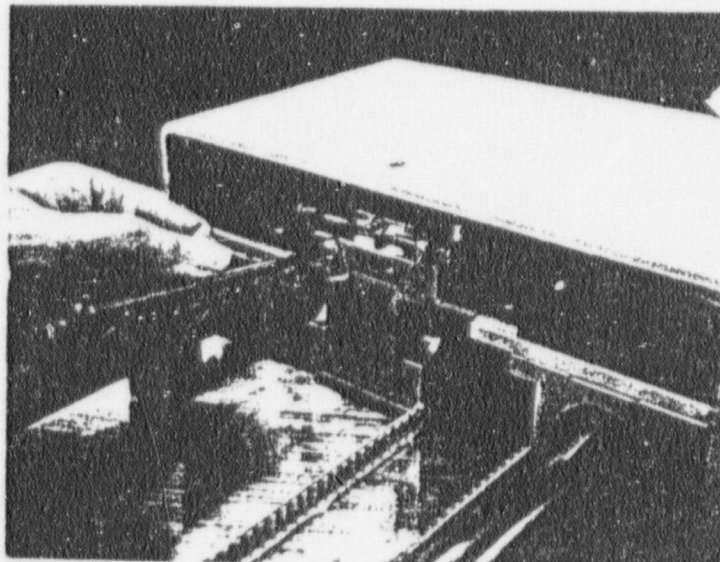


Figure 29

The source holder has its own shutter. Once the source holder is correctly installed in its chamber, its shutter is opened.

The dose rate at the surface of the holder for a typical Gd-153 1 Curie source is 5 mr/hr. The installation procedure is expected to involve a maximum of 1 minute of direct handling of the source holder. As a result, the person doing the installation typically will receive a finger dose of 0.1 mr.