



12935 South Gregory Street
Blue Island, Illinois 60406
312-597-2000

August 22, 1985

Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Reference: License No. 12-10094-01

Gentlemen:

We wish to amend our By-product Materials License to allow for the use and possession of Gd-153 sources in a bone mineral analyzer. Given in attachments to this letter is information about the source, device, authorized users, and radiation safety precautions we wish to observe.

Should you have any questions, please call either Mr. Emil Ernest, CNMT at (312)597-2000 or Mr. Gerald Wicks, Consulting Health Physicist at (312)564-3330.

Our check for \$120.00 is enclosed.

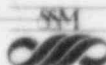
Sincerely,

Bryant R. Hanson
Executive Director

8511180208 850924
REG3 LIC30
12-10094-01 PDR

enclosures

Applicant Sept 16/85
Check No. 121594
Amount/Fee Category \$120 (70)
Type of Fee AMD
Date Check Rec'd 9/16
Received by SK / gpe



A MEMBER OF THE SISTERS OF ST. MARY HEALTH CARE SYSTEM

RECEIVED
SEP 09 1985
REGION III

LPM
SEP 16 1985

CONTROL NO. 79720

ST. FRANCIS HOSPITAL

12935 South Gregory Street

Blue Island, Illinois 60406

312-597-2000

PURCHASE
ORDER NO.

PO- 004697

THE ABOVE NUMBER MUST APPEAR ON ALL
CARTONS, INVOICES, SHIPPING DOCUMENTS
AND CORRESPONDENCE RELATIVE TO THIS
ORDER

U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

PLEASE ENTER OUR ORDER FOR THE FOLLOWING
ITEMS: SUBJECT TO ALL CONDITIONS ON THE
FACE AND BACK OF THIS ORDER

TERMS
AND
CONDITIONS

It is requested that packing slip be securely attached to exterior of shipping carton.

This Order may not be modified or changed orally or in any other manner except in writing signed by the authorized representative of the Purchasing Department.

All merchandise must be delivered to Receiving between 8:00 A.M. - 4:00 P.M.

Transportation charges shall be prepaid to point of delivery specified, and add to invoice. Any prepaid charges must be supported at time of invoice by freight or express receipts including Hospital purchase order number.

Acceptance of all goods and materials furnished under this Order are subject to buyers inspection at point of use. Payment for materials delivered prior to inspection shall not constitute acceptance thereof.

The buyers reserve the right to return any or all items not deemed acceptable for any reason by mutual agreement and in compliance with seller policy regarding returns.

The delivery date of items involved with construction must be confirmed with the Purchasing Office 5 working days before delivery. Any deliveries on this purchase order must be confirmed 5 working days before delivery if the items require a mechanical or construction connection to the building.

It shall be the responsibility of the seller to arrange for returning items shipped in error or duplication at no cost to the buyer in a period of time not exceeding normal delivery shall be rendered.

The seller must advise the buyer by return mail of extended delivery times or back order situations of items in this order.

Non-compliance with the instructions and conditions of this Order will be cause for refusal of shipment.

St. Francis Hospital is a non-profit institution exempt from the Retailers' Occupation Tax and the Service Occupation Tax and the Service Use Tax.

We will not be responsible for goods or services delivered or rendered except on a properly authorized Purchase Order.

This Purchase Order is subject to all terms and conditions as shown on the face and back.

DATE OF ORDER		DATE REQUIRED	TERMS	SHIP VIA	F O B	DEPARTMENT	
8/23/85		ASAP				Nuclear Medicine	
ITEM NO.	QUANTITY UNIT	DESCRIPTION			ACCT	PRICE PER UNIT	AMOUNT
		Ammendment Fee for License No. 12-10094-01			780726		120.00
		Gd-153 Sealed Source					
		CHECK ENCLOSED: \$120.00					
		LETTER ENCLOSED					
						TOTAL	120.00

AUG 26 1985

BY

AUTHORIZED SIGNATURE

VENDOR

SEP 9 1985

BUYER'S TERMS AND CONDITIONS OF PURCHASE AS AMENDED 1/80

1. **ACCEPTANCE:** This order is for the purchase and sale of the goods (herein referred to as "the Articles") and/or services described on the attached purchase order and is the Hospital's offer to Seller. Acknowledgement hereof by Seller to Buyer shall constitute Seller's acceptance of such order, including all of the terms and conditions herein set out. In the absence of such acknowledgment, commencement of delivery of the Articles and/or services and acceptance of such deliveries by Buyer shall constitute a firm contract on the terms and conditions hereof. This order is subject to the following terms and conditions and no others unless there is a signed overriding agreement between the parties prepared by Hospital.
2. **PACKING:** The Articles shall be packed and shipped by Seller in accordance with Hospital's instructions and good commercial practice and so as to insure that no damage shall result from weather or transportation.
3. **WARRANTY—PRODUCT:** Seller warrants that all the Articles will be free from defects in material and workmanship, will conform to specifications, drawings and other descriptions and to accepted samples and, if ordered for a stated purpose, will be fit for such purpose. Seller also warrants that to the extent the Articles are not manufactured pursuant to detailed designs furnished by Hospital they will be free from defects in design, and agrees to make such changes, adjustments or replacements as necessary to meet the guarantee, at no cost to the Hospital. Such warranties, including warranties prescribed by law, shall run to Hospital, its successors, assigns and heirs, and to users of the Articles, for a period of one year after delivery or such longer period as may be prescribed by law or additional agreement.
4. **WARRANTY—PRICE:** Seller warrants that prices that are charged Hospital, as indicated on the front side hereof, are no higher than prices charged on orders placed by others for similar conditions subsequent to the last general announced price change. In the event Seller breaches this warranty, the price of the Articles shall be reduced accordingly retroactive to date of such breach.
5. **TERMINATION:**
 - a. Hospital may cancel this order, in whole or in part, without liability to Hospital, if deliveries are not made at the time and the quantities or conditions hereof.
 - b. Hospital may terminate this order in whole or part at any time for its convenience by notice to Seller in writing. On receipt by Seller of such notice, Seller shall, and to the extent specified therein, stop work hereunder and the placements of subcontracts, terminate work under subcontracts outstanding hereunder, and take any necessary action to protect property in Seller's possession in which Hospital has or may acquire an interest. Any termination claim must be submitted to Hospital within sixty (60) days after effective date of termination.
 - c. Any cancellation or termination by Hospital, whether for default or otherwise, shall be without prejudice to any claims for damages or other rights of Hospital against Seller.
 - d. Hospital may cancel this order, in whole or in part, without liability to Hospital, if deliveries are not made at the time and in the quantities specified or in the event of a breach or failure of any of the other terms or conditions hereof.
6. **CHANGES:** Hospital at any time may make changes in the quantities ordered or in the specifications of drawings relating to the Articles or may exchange or amend any other term or condition of this order, in which event an equitable adjustment will be made to any price, time of performance and/or other provisions of this order required to be changed thereby. Any claim for such an adjustment must be made within fifteen (15) days from date of receipt by Seller of such change.
7. **COMPLIANCE WITH LAWS:** In filling this order, Seller shall comply with all applicable federal, state and local laws and government regulations and orders. Seller specifically warrants and guarantees to Hospital:
 - a. that the Articles are in compliance with Sections 5 and 12 of Federal Trade Commission Act, and are properly labeled as to content as required by applicable Federal Trade Commission Trade Practice Rules;
 - b. that all Articles furnished hereunder will be produced and sold in compliance with all applicable requirements of the Fair Labor Standards Act, as amended, including Sections 5, 7, and 12, and the regulations and orders issued under Section 14, thereof, and that it will certify such compliance on each invoice submitted in connection with this order;
 - c. that the Articles are in compliance with the Consumer Product Safety Act of 1972;
 - d. that the Articles are not manufactured or sold in violation of the Occupational Safety and Health Act of 1970;
 - e. that the Articles are not manufactured or sold in violation of the Medical Device Amendments of 1976.
8. **INDEMNITY AND INSURANCE:**
 - a. Seller shall defend, indemnify and hold harmless Hospital, its employees and users of the Articles, from and against any claim, loss, damage or expense arising out of the purchase and/or use of the Articles purchased hereunder and/or arising out of Seller's (or its subcontractor's) work or performance hereunder and shall procure and maintain liability insurance, with contractual liability coverage, with minimum limits of \$250,000/\$500,000/\$100,000 or such higher limits as Hospital shall reasonably request. Seller shall, on or before delivery of the Articles purchased hereunder, furnish to Hospital a Certificate of Insurance evidencing the foregoing coverages and limits.
 - b. Seller shall defend, indemnify and hold harmless Hospital from and against the assessment by any third party of any liquidated damages or proven actual damages arising out of the failure of Seller to timely deliver the Articles purchased hereunder.
 - c. Seller shall defend, indemnify and hold harmless Hospital, its employees and users of the Articles from and against any claim loss (including the cost of any Articles lost by libel, condemnation or voluntary recall), damage arising out of any claim or finding by the United States of America or any state or local government or any agency or instrumentality thereof that the Articles are not herein guaranteed and warranted.
9. **ASSIGNMENT:** Seller shall not assign this order or any interest herein, including any performance or any amount which may be due or may become due hereunder, without Hospital's prior written consent.
10. **SUBCONTRACTING:** If any Articles are to be made to Hospital's design, and/or services described on the front hereof, all subcontracting by Seller with respect thereto shall be subject to Hospital's written approval which shall not be indecisiminally withheld.
11. **ADVERTISING:** Seller shall not advertise or publish the fact that Hospital has placed this order without Hospital's prior written consent except as may be necessary to comply with a proper request for information from an authorized representative of any government unit or agency.
12. **CONTROLLING LAW:** This order and the performance of the parties hereunder shall be controlled and governed by the law of the state shown in Hospital's address on the front side hereof.
13. **NOTICE OF LABOR DISPUTES:** Whenever an actual or potential labor dispute is delaying or threatens to delay the timely performance of this order, Seller shall immediately give notice thereof, including all relevant information with respect thereto, to Hospital. If a subcontract is involved, Seller shall insert the substance of this paragraph in any subcontract hereunder so that each subcontract shall provide that in the event its timely performance is delayed or threatened by delay by any actual or potential labor dispute, the subcontractor shall immediately notify Seller of all relevant information with respect thereto.
14. **RISK OF LOSS:** Risk of loss or damage to the Articles shall be on Seller until said Articles have been delivered to and accepted by Hospital notwithstanding any other terms contained herein. All Articles will be received by Hospital subject to its right of inspection and rejection. Hospital shall be allowed a reasonable period of time to inspect the Articles and to notify Seller of any nonconformance with the terms and conditions of this order. Hospital may reject any Articles which do not conform to the terms and conditions of this order. Articles so rejected may be returned to Seller, or held by Hospital, at Seller's risk and expense.
15. **GENERAL:** All warranties shall be construed as conditions as well as warranties. No waiver of a breach or of any provisions of this order shall constitute a waiver of any other breach or provision. No modification, change in, or departure from, or waiver of the provisions of this order shall be valid or binding unless approved by Hospital in writing. This order shall constitute the entire agreement between the parties.

**AUTHORIZED USERS AND TRAINING AND EXPERIENCE
FOR THE BONE MINERAL ANALYZER**

The following physicians will be using the Lunar DP3 Spine/femur Scanner:

Luke Pascale, M.D.

John W. Laude, M.D.

For training and experience of these physicians, please refer to License No. 12-10094-01. Furthermore, these physicians will receive training from the Lunar Radiation Corp.

Each Lunar Bone Mineral Scanner is installed by a qualified expert who will provide two days of installation and training. This training covers source installation, wipe testing, scan operations and data analysis and interpretation. The institution's Radiation Safety Officer must be present for instruction on source replacement and wipe testing.

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RADIOACTIVE MATERIAL FOR MEDICAL USE

[Not Listed in Item 6a]

	<u>Element and Mass Number</u>	<u>Chemical / Physical Form</u>	<u>Manufacturer & Model No.</u>	<u>Maximum Source Activity</u>
1.	Gd-153	Gd O ₂ (sealed)	Gulf Nuclear Model GD-1	1500 mCi
2.	Gd-153	Gd O ₂ (sealed)	New England Nuclear Model #NER-430	1500 mCi
3.	Gd-153	Gd O ₂ (sealed)	Amersham Corp. Model # GDCCY1	1500 mCi

***NOTE:**

For continuity of use, the total possession limit requested is 2000 mCi and includes the summed activity of a new source and decayed sources. (Useful life of one source is 12 to 18 months according to the manufacturer. Old, unusable sources will be held for decay to background radiation levels in the Radioactive Decay Room as indicated in Item 18 of our license application dated October 29, 1980.)

The Gd-153 source will be used in a bone mineral analyzer sold by Lunar Radiation Corp. of Madison, Wisconsin. The model number is DP-3 and the NRC device registration number is NR-430-D-101-S.

The Gd-153 sealed source is sold by:

1. Gulf Nuclear Inc.
202 Medical Center Boulevard
Webster, Texas 77598
Phone: (713)332-3581
2. DuPont-New England Nuclear
331 Treble Cove Road
North Billerica, Massachusetts 01862
Phone: 800-225-1572
3. Amersham Corp.
2636 Clearbrook Drive
Arlington Heights, Illinois 60006
Phone: (312)593-6300

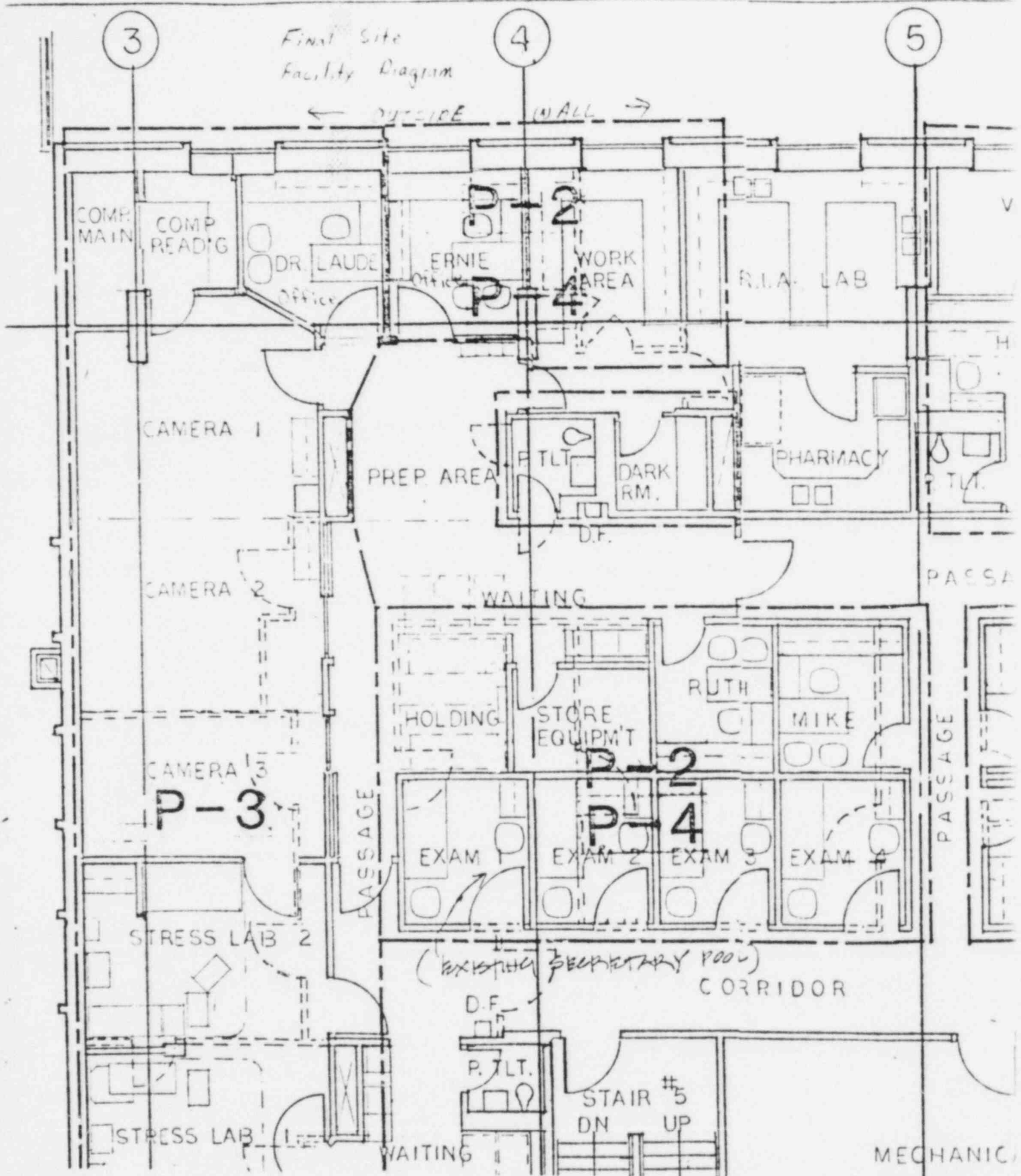
FACILITIES AND EQUIPMENT

The bone mineral analyzer will be located in the Nuclear Medicine Department in the work area.

Old, unusable Gd-153 sources will be stored in a lead container in the department's radioactive decay area.

St. Francis Hospital
Blue Island, Illinois

License No. NRC 12-10094-01
State of IL IL-00160-01



LUNAR RADIATION CORP.

DP3 SPINE/FEMUR SCANNER and SP2 FOREARM SCANNER SPECIFICATIONS

Computer

NorthStar Advantage

Dimensions: 28x51x32cm (20kg)

Processor: Z80A CPU and INTEL 8035; option IBM compatible

Display: 28cm diagonal P31 Phosphor; 1920 character (24 lines x 80 characters); graphics 240x640 pixels bit-mapped; screen dump to printer

Disks: Two 5-1/4" floppy diskette drives (double-sided, double density); 360K L₁ (10 sector); holds 25 spine or femur scans or 55 forearm scans per diskette

Nuclear Instrumentation

High voltage: Programmable 600 to 1600V

Amplifier: High-speed (0.25 microsec shaping time)

Dual channel analyzer: Low-drift fast analyzers

Dual scalars: 10 MHz scalars (1C-bit)

Timer: Crystal-controlled programmable

Detector: Collimated NaI (T_L) scintillation detector with Blackali Cathode

Motors and Control

Motors: 4-phase stepping motors

Control: Programmable controller, menu-driven step interval and speed

Scan Table (for DP3)

Dimensions: 183 x 81 x 69cm (50kg)

Materials: 2.5 x 5cm chrome plated steel legs, laminate covered wood top

Console Table (for both DP3 and SP2)

Dimensions: 152 x 76 x 69cm (30kg)

Materials: 2.5 x 5cm chrome plated steel legs; laminate covered wood top

Scanner Mechanism

DP3-Dimensions: 60 x 60 x 25cm metal enclosure below table (30kg)

SP2-Dimensions: 56 x 54 x 46cm metal enclosure

Source access: Through locked table top

Software

Operating system, graphics and BASIC are standard.

Compiled programs include: spinal scanning, femoral scanning, quality control; reanalysis of data from diskette

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Warranty

Ninety day complete parts and labor coverage warranty. One-year parts warranty on Lunar Radiation components (scanner and counting electronics).

Service Contracts

Extension of the complete warranty service can be obtained under a service contract. Service contracts provide for the continued operation of your systems at a predictable cost. Benefits include one-day replacement service in case of failure and on-site service if necessary.

Radionuclide sources

¹⁵³Gd (1 Ci) sources are supplied by Gulf Nuclear of Webster, Texas (713-332-3581) for approximately \$6700 and can be used for 12-13 months.

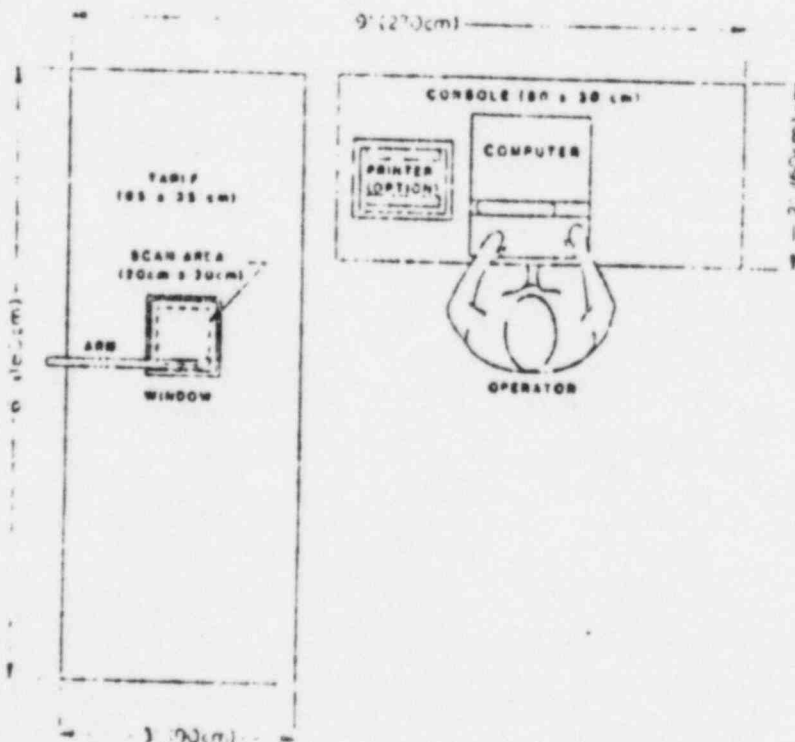
¹²⁵I sources (200mCi) are supplied by Atomic Energy of Canada, Ltd. (613-592-2790, ext. 2048) for about \$600 and can be used for 6 months.

N.R.C. Device Registration: DP3 NR-430-D-101-S, SP2 NR-430-D-102-S. 8-hours training required for licence.

Delivery

30 days ARO.

System Configuration (typical)



**PERSONNEL TRAINING PROGRAM
FOR THE BONE MINERAL SCANNER**

The technologist(s) will be instructed in the use of the Lunar DP-3 Spine/Femur Scanner and the radiation safety aspects of the Gd-153 sealed source. The instructions will be provided by a representative of the Lunar Radiation Corp., and will include the configuration of the source, safe removal of the source, safe storage of the source, the installation of the source and wipe testing of the source.

**GENERAL RULES AND THE SAFE USE OF RADIOACTIVE MATERIALS
FOR THE BONE MINERAL SCANNER**

Operating instructions given by Lunar Radiation Corp.
for the DP-3 Spine/Femur Scanner (NRC device Registration
No. NRC-430-D-101-S) will be followed.

ITEM 15 (8/85)

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AREA SURVEY PROCEDURE

FOR THE BONE MINERAL SCANNER

The DP3 Spine/Femur Scanner from Lunar Radiation Corp. containing the Gd-153 sealed source will be surveyed once a week using a low-level GM survey meter on contact with the external surface of the source housing and at three feet from the source housing location. Results will be recorded.

WASTE DISPOSAL

GD-153 sealed sources received by Gulf Nuclear Corp., Amersham Corp or DuPont-New England Nuclear, will either be held for decay to background radiation levels or returned to the source distributor.

A low-level open window survey meter probe will be used to survey the unshielded Gd-153 sealed source(s) prior to disposal by bringing the probe into contact with the Gd-153 source(s). If the unshielded Gd-153 sealed source(s) survey results are equal to background radiation levels in an unrestricted area, the source(s) will be disposed. DOT and NRC regulations will be followed if the sources are returned to the distributor. Records of source disposal or return will be kept.

ITEM 18 (8/85)

CONTROL NO. 79720