NRC FORM 313M (9-81) 10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved by OMB 3150-0041 Expires 9-30-83

INSTRUCTIONS - *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Rockford Memorial Hospital
2400 North Rockton Avenue
Rockford, Illinois 61101

TELEPHONE NO.: AREA CODE (815) 968 - 6861

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

Same

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Richard Goodman

TELEPHONE NO.: AREA CODE (815) 968-6861 X5545

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

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 12-02530-03
c. ☐ RENEWAL OF LICENSE NO. _____

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

Please refer to attached Item #4

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Richard Goodman, M.S.
[Please refer to revious application for his training and experience]

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		

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

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Gadolinium-153	$Gd\ O_2$	1500 mCi (Authorization requested for two sources, each 1500 mCi)	As a sealed source in a Bone Mineral Scanner, Model DP3, sold by Lunar Corp., Madison, Wisconsin.
PLEASE REFER TO ITEM #6b attached			

Log ... Remitter ... Check No. ... Amount $150 ... Fee Category ... Type of Fee ... Date Check Rec'd. ... Date Completed ...

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INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

For Item Nos. 7, 8, 10, 13, 14, 16, please refer to our previous applications for license No. 12-02530-03.

7. MEDICAL ISOTOPES COMMITTEE	15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*
[ ] Names and Specialties Attached; and	[ ] Appendix G Rules Followed; or
[ ] Duties as in Appendix B; or *(Check One)*	[X] Equivalent Rules Attached
[ ] Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*
8. TRAINING AND EXPERIENCE	[ ] Appendix H Procedures Followed; or
[ ] Supplements A & B Attached for Each Individual User; and	[ ] Equivalent Procedures Attached
[ ] Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES *(Check One)*
9. INSTRUMENTATION *(Check One)*	[ ] Appendix I Procedures Followed; or
[ ] Appendix C Form Attached; or	[X] Equivalent Procedures Attached
[X] List by Name and Model Number	18. WASTE DISPOSAL *(Check One)*
10. CALIBRATION OF INSTRUMENTS	[ ] Appendix J Form Attached; or
[ ] Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	[X] Equivalent Information Attached
[ ] Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*
[ ] Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	[ ] Appendix K Procedures Followed; or
[ ] Equivalent Procedures Attached	[ ] Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	20. THERAPEUTIC USE OF SEALED SOURCES
[X] Description and Diagram Attached	[ ] Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	[ ] Appendix L Procedures Followed; or *(Check One)*
[X] Description of Training Attached	[ ] Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)
[ ] Detailed Information Attached	[ ] Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS
[ ] Appendix F Procedures Followed; or	[ ] Detailed Information Attached
[ ] Equivalent Procedures Attached	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b
	[ ] Detailed Information Attached

CONTROL NO. 8090(4)

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	Siemens	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Siemens	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL: N / A

MAILING ADDRESS:

CITY | STATE | ZIP CODE

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

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

26. CERTIFICATE
(This item must be completed by applicant)

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

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

(1) LICENSE FEE CATEGORY:

(2) LICENSE FEE ENCLOSED: $ 120.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* John H. Loebl

(1) NAME *(Type or Print)*: John H. Loebl

(2) TITLE: Assistant Vice President-Operations

c. DATE: March 12, 1986

NRC FORM 313M (9 81)

CONTROL NO. 80904

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

AUTHORIZED USERS AND TRAINING AND EXPERIENCE FOR THE BONE MINERAL ANALYZER

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

1. Alan Kaplan, M.D.
2. Ervin G. Hrasky, M.D.
3. Bradley D. Munson, M.D.
4. Kenneth Baliga, M.D.

For training and experience of these physicians please refer to License No. 12-02530-03. Furthermore, these physicians will receive training from the Lunar Radiation Corp.

Training:

Each Lunar Bone Mineral Scanner is installed by a qualified expert from the Lunar Corp. who will provide two days of installation and training. This training covers source installation, source exchange, wipe testing, scan operations and data analysis and interpretation.

1. The training provided to the proposed users of the of the Scanner will include demonstration and actual "hands-on" training in -
   a] Installing and replacing the Gadolinium-153 source,
   b] Leak testing the source,
   c] Preparing the decayed source for shipment, and
   d] Proper storage of the source when not in the above Scanner.

2. For step-by-step procedures for the exchange of Gadolinium 153 sealed source, please refer to the attached Appendix A. This source exchange will be conducted by, or under the supervision of, one of the licensed physicians listed above or the Radiation Safety Officer.

3. The Scanner will be serviced by a representative of the Lunar Corp., Madison, Wisconsin.

4. The whole body and extremity monitoring will be worn during source exchange.

Gadolinium-153

RADIOACTIVE MATERIAL FOR MEDICAL USE

(Item 6b)

	Element and Mass Number	Chemical / Physical Form	Manufacturer & Model No.	Maximum Source Activity
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

Or any sealed source approved by the NRC for use in such a device.

*NOTE: For continuity of use, the total possession limit requested is for two sources, each of 1500 mCi. Useful life of one source is 12 to 18 months according to the manufacturuer. Old unusable sources will be held in the decay area as indicated in Item 18 of our previous license application, until it is shipped for disposal.

The Gd-153 source will be used in a bone mineral analyzer sold by Lunar Radiation Corp. of Madison, Wisconsin. The model number is DP3 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.
   2635 Clearbrook Drive
   Arlington Heights, Illinois 60006

ITEM 9

INSTRUMENTATION

Please amend to add -

One - Lunar DP3 Spine/Femur Scanner using a Gadolinium-153 sealed source (1 Curie).

ITEM 9

FACILITIES AND EQUIPMENT

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

Old, unusable Gd-153 sources will be stored in a lead container in the department's radioactive decay area until shipped to the manufacturer for disposal.

PERSONNEL TRAINING PROGRAM FOR THE BONE MINERAL SCANNER

The technologist(s) will be instructed in the use of the Lunar DP3 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.

Specifically, the training will include demonstration and actual "hands-on" training in:

a] Installing and replacing the Gadolinium 153 source,
b] Leak testing the source,
c] Preparing the decayed source for shipment, and
d] Proper storage of the source when not in the bone mineral scanner.
e] Whole body and extremity monitoring will be worn during source exchange.

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

The operating instructions given by Lunar Radiation Corp for the DP3 Spine/Femur Scanner (NRC device Registration No. NRC-430-D-101-S) will be followed. For details please see attached Item No. 8 and 12.

1. To secure the source -

   The department will be locked when unattended by authorized personnel. Similarily, the Gd-153 source, when not in the Scanner, will be stored in the radioactive materials storage area behind lead shielding and the door to the area will be locked when unattended by authorized personnel.

2. The source will be leak tested once every six months and the wipes will be analyzed by an organization specifically authorized by the Commission to perform such services.

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. Results will be recorded.

WASTE DISPOSAL

Gd-153 sealed sources received from Gulf Nuclear Corp., Amersham Corp. of DuPont-New England Nuclear, will be held in storage until shipped to an authorized organization for disposal of the source.

The source will be held in storage in one of our radioactive materials decay areas, either in the Nuclear Medicine or Radiation Oncology Department. The source will have lead shielding sufficient to maintain radiation levels less than 2 mR/hr in contact with the shielding material.

The source will be shipped for disposal in a container similar to the one used for shipping the source to the hospital by the manufacturer of the source. Applicable DOT and NRC regulations will be followed for the shipment of the source.

Records of source disposal will be kept.

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 5-¼" floppy diskette drives (double-sided, double density); 360K byte per diskette (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 scalers: 10 MHz scalers (16-bit)

Timer: Crystal-controlled programmable

Detector: Collimated NaI (Tl) scintillation detector with Bialkali 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

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

153-GD (1 Ci) sources are supplied by Gulf Nuclear of Webster, Texas (713-332-3581) for approximately $6700 and can be used for 12-18 months.

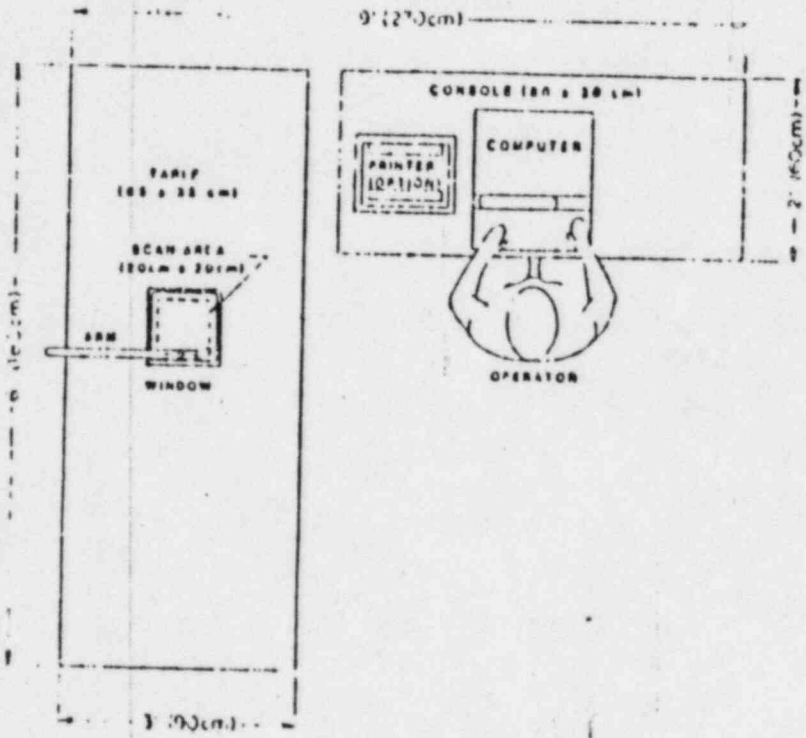
125-I sources (200mCi) are supplied by Atomic Energy of Canada, Ltd. (613-592-2790, ext. 2048) for about $600 and can be used for 6 months.

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

Delivery

30 days ARO.

System Configuration (typical)



APPENDIX A

RADIATION SAFETY FOR USERS OF LUNAR BONE MINERAL ANALYZERS

OUTLINE

TABLE OF FIGURES

A. Basic Principles

A.1 Radioisotopes

While a bone mineral analyzer is scanning a patient the system uses x-ray radiation to acquire information about the quality of the bone. The type of radiation used in the LUNAR bone analyzers is similar to that used in conventional diagnostic radiology, however, the source of the radiation is different. A conventional x-ray film is made using radiation that is produced when an electrical voltage is applied to the x-ray machine. The x-ray radiation used in the bone analyzer comes from a radioisotope, Gd-153, I-125 or Am-241. These sources are always "on" and emitting radiation but this radiation is in part shielded by the container in which the source is located. They must be handled by a professional trained in the use of radiation. Radioisotopes are in an unnaturally excited state and undergo nuclear and atomic change to become stable. This nuclear change results in the emission of radiation, x-rays and gamma-rays.

A.2 Radioactive Decay

These changes occur spontaneously to change the unstable parent element to a stable daughter element. This change is called radioactive decay and may result in the emission of an alpha particle, a beta particle or gamma rays. Radioisotopes are always decaying so the amount of the parent is constantly decreasing. Different isotopes decay at different rates. The time it takes to reduce the amount of a radioisotope to half of the original amount is termed the half-life. The amount of radioactive material is measured in units of curies (Ci). The half-life of Gd-153 is 242 days and the recommended starting activity for sources in a bone analyzer is 1 Ci (1000 mCi). The half-life of I-125 is 60 days while that of Am-241 is very long, 458 years.

At the end of 8 months (240 days) the remaining activity of a Gd-153 source will be 500 mCi. As the amount of Gd-153 decreases, the information that the bone analyzer acquires decreases and the precision of the measurement becomes unacceptable. The Same is true for I-125 but the half-live is much shorter. The useful livetime of these sources is typically 2-3 half-lives depending on application. Most users will replace the Gd-153 source at 12-18 months (when the activity is 120 to 200 mCi) and the I-125 source at 6 months (when activity is 25 mCi). Users often retain sources on premise for a period after withdrawal form use to allow further decay before returning the source for disposal.

A.3 External Radiation

This radiation is called ionizing radiation and subjects the patient to an external radiation exposure. This is in contrast to an internal exposure where the radioisotope is within the patient. The radioisotope used in the bone analyzers is physically exterior to the patient. There is never any radioactive material present in the patient either during or after a scan. X-rays and gamma-rays are packages of energy without that travel at the speed of light. Some of these rays are stopped in the patients body and others pass through without any interactions. Differences amoung patients in the amount of radiation stopped by bone allows the bone mineral analyzer to differeniate good from poor bone.

A.4 Radiation Exposure

When not scanning a patient or standard the radiation beam is occluded by a lead shutter. During a scan this shutter is open and the radiation area confined to a narrow (4 mm) beam at the surface of the patient table for both Gd-135 and I-125. The confinement of the radiation is achieved by the source holder and results in radiation levels within the room far below the level where additional shielding would be needed to protect non-radiation worker or pregnant women. The actual amount of radiation exposure received by the patient and the operator are presented in Appendix A of the User Manual.

In general, the exposure received by a patient during a LUNAR I-125 forearm rectilinear scan or a Gd-153 spine scan is approximately 12-15 mrem which is comparable to a typical chest x-ray. During a spine scan the operator exposure at one meter from the patient is approximately 0.012 mrem. For a comparison, the average per capital background exposure is 170 mrem. These comparisons are only presented to offer an assessment of the relative risk of bone mineral analyzers. The stated values of approximately 12-15 mrem is for a new radioactive source. During actual practice the typical patient exposure will be about half this value.In actual practice, all radiation exposures must be kept as low a practical and all medical use of radiation must occur judiciously.

B. Radiation Regulations

B.1 Licensing

The possession and uses of I-125, Am-241 and Gd-153 radionuclides for bone mineral scanning requires licensing from the appropriate state or federal authority. The Nuclear Regulatory Commission administers licenses to individuals or institutions within certain states*. The remaining states, the so called "agreement states", administer licenses to their own residents. Although the following information covers only the NRC regulation, most state radiation control agencies have similar requirements. Individuals within agreement states must contact their appropriate state agency for licensing information.

B.1.a License amendment

Most major hospitals have broad NRC licenses that allow possession of all radionuclides with atomic number 1 to 83 for medical use. The total amount allowed for an individual radionuclide will vary with institution and requires a check of the particular institution's license. If the licensed amounts are compatible with those listed below in section B.1.c then the license need not be amended. However, since broad licenses may also have a limit on the total radioactivity, it may be prudent to amend for the specific inclusion of I-125 and Gd-153 for bone mineral analyzers.

Institutions with Group VI licensing do not have to amend for use of I-125. However, Gd-153 is currently not a Group VI isotope and its use requires a license amendment. Institutions without broad licensing or Group VI must amend their current licenses to include the use of sealed radionuclide sources for bone mineral analyzers. The institution's Radiation Safety Officer will direct the filing of an amended NRC form 313. The information found in section B.1.c will assist in answering item 5 and 6 of form 313.

B.1.b New Licenses

By definition, broad medical licensees and Group VI licensees have users who have adequate training and experience to use radiation. Individuals planning to use LUNAR's bone mineral analyzer who lack the required training and experience must approach their institution for required training.

*
Connecticut, Delaware, Illinois, Indiana, Iowa, Maine, Mass, Maine, Michigan, Minnesota, Missouri, Montana, New Jersy, Ohio, Oklahoma, Pennsylvania, South Dakota, Utah, Vermont, Virginia, West Virginia, Wisconsin, Whyoming.

Each LUNAR bone mineral analyzer is installed by qualified experts who provide two days of installation and training. This training covers source installation, wipe testing, scan operations, and data analysis and interpretation. The institutions Radiation Safety Office must be present for instruction on source replacement and wipe testing.

Institutions and individuals who are applying for the first time for specific licensing must demonstrate that the proposed physician-users have adequate training (NRC Policy and Guidance Directive FC 83-24). This may be achieved by one of the following:

a. Are licensed by the NRC or agreement state to use byproducts material specified in one or more of Groups I through VI, inclusive of Section 35.100, or

b. Are certified by the American Board of Nuclear Medicine, or the American Board of Radiology in Diagnostic Radiology, with Special Competence in Nuclear Radiology (certification as a British "Fellow of the Faculty of Radiology" or "fellow of the Royal College of Radiology" or Canadian Certification form the Royal College of Physicians and Surgeons on radiology may be accepted in lieu thereof), or

c. As a minimum, have received a total of 8 hours of training as described in Directive FC 83-24.

The 8 hours of training required in item c must be provided by a certified Health Physicist. Upon request, LUNAR will provide a list of national and regional Health Physics Consultanting groups. Alternatively, we suggest referring to ones phone directory for local health physics support.

A health physicist can assist in training, licensing, source replacement and disposal, and wipe testing.

B.1.c Licensing information

The appropriate source information as determined by intended clinical use should be included in item 5 of NRC form 313.

Element and mass number	chemical and/or physical form	manufacturer and model number	amount
125-I	ion exchange	AECL C324	240 mCi each 300 mCi total
153-Gd	GdO_2	Gulf Nuclear Model GD-1	1200 mCi each 1500mCi total
241-Am	ceramic bead	Amersham	60 mCi each

During normal use only one isotope per unit will be on site. For continuity of patient scanning, the total amount listed in the license must include the summed activity of a newly received source and the decayed source to be returned to the source manufacturer.

The sealed sources listed above will be used in one of two types of bone mineral analyzers. There must be a direct reference to the NRC device registration number.

source	device	NRC device registration
125-I	SP2	NR-430-D-102-S
153-Gd	DP3	NR-430-D-101-S
241-Am	SP2	To be applied for

B.2 Receiving Sources

The transport of radioactive materials is governed primarily by Title 10 and Title 49 Code of Federal Regulations (CFR). The Radiation Safety Officer (RSO) must inspect packages containing byproduct material within three hours after receipt or 18 hours if received after normal working hours (10 CFR 20.205). The RSO should be conscious of expected delivery dates so that shipments can be quickly inspected. The inspection procedure is included at the end of this discussion.

B.2.a General Rules

The following definitions are used in Federal regulations and in the procedure forms:

Package means the packaging plus the contents of radioactive materials as presented by the shipper for transportation.

Packaging means the assembly of the container and other components necessary to assure compliance with prescribed regulations.

Radioactive materials means any material or combination of materials which spontaneously emits ionizing radiation and which has a specific activity in excess of 0.002 microcuries per gram of material (49CFR173.389(e)).

Removable Radioactive Contamination means radioactive contamination which can be readily removed in measurable quantities by wiping the contaminated surface with absorbent material. The measurable quantities are not considered significant if the average amount of radioactive contamination as measured on the wiping material does not exceed: (49CFR173.389(f) and 173.398(a)).

1. 10^{-11} Ci of beta-gamma/cm^2 (22,000dpm/100cm^2) (220dpm/100cm^2) for natural or depleted uranium or natural thorium.

2. 10^{-10} Ci of beta-gamma/cm^2 (22,000dpm/100cm^2), and 10^{-11} Ci of alpha/cm^2 (2,200dpm/100cm^2) for natural or depleted uranium or natural thorium.

Transport Group means the number to be placed on a package label to designate the degree of control to be exercised by the carrier during transportation and indicating the highest radiation exposure rate in milliRoentgen per hour at three feet from any accessible external surface of the package (49CFR173.389(i)).

Types A (liquid form) and B (sealed sources) Quantities of Radioactive Materials means a quantity the aggregate radioactivity of which does not exceed the following amounts: (49CFR173.389(i)).

Transport Group	Type A Quantity in Curies	Type B Quantity in Curies
I	0.001	20
II	0.05	20
III	3	200
IV	20	200
V	20	5,000
VI and VII	1,000	50,000

General requirements for radioactive materials packages include a seal which is not readily breakable, to provide evidence that the package has not been illicitly opened. Packages must not have any dimensions smaller that 4 inches. Shielding must be sufficient to limit the exposure rate at any exposed surface of the package to 100 mR per hour and to limit the exposure rate at 3 feet from any exposed surface to 10 mR per hour. Specific requirements for Type A and B packages must be met and if interested consult 49CFR for details. Labels for

packages of radioactive materials must be diamond shape, in colors specified in this section, with each side at least 4 inches long. Printing must be in black inside a black line border measuring at least 3.5 inches on each side and as shown in this section (49CFR173.414). Two labels must be placed on the package on opposite sides so that one label is always visible.

"Radioactive White-I" label must be white in color. The single vertical bar on the lower half of the label must be bright red in color. Labels must be applied on two opposite sides of each package having an exposure rate not exceeding 0.25 millirem per hour at any point on the external surface of the package.

"Radioactive Yellow-II" must have the upper half a bright yellow and the bottom half white. The two vertical bars on the lower half of the label must be bright red in color. Labels must be applied on two opposite sides of:

1. Each package having an exposure rate not exceeding 5 milliRoentgen per hour at any point on the external surface of the package and not exceeding 0.5 milliRoentgen per hour at 3 feet from the external surface of the package; or

2. Each package for which the transport index does not exceed 0.5 milliRoentgen at any time during transportation.

"Radioactive Yellow-III" labels must have the upper half a bright yellow and the bottom half white. The three vertical bars on the lower half of the label must be bright red in color. Labels must be applied on two opposite sides of each package having a surface exposure rate not exceeding 100 milliRoentgen per hour and not exceeding 10 milliRoentgen per hour at 3 feet from the external surface of the package (49CFR173.399).

B.2.b Procedures

The RSO should supervise the unpacking of byproduct material shipments. The package should be placed on a nonporous surface when it arrives at the factory. Protective gloves and a lab coat should be worn when processing packages.

NOTE: The Transport Group on new sources you receive would be I for 241-Am, IV for 153-Gd, and III for 125-I.

1. Monitor the package for radiation fields using the GM meter. The reading should be taken at each surface and at 3 feet from the surface. The readings should correspond to the Transportation Index rating. See previous discussion for information necessary for determining transport index. If the radiation level is above 200mrem on the surface or 10mrem 3 feet from the surface then the NRC must immediately be notified.

2. Examine the exterior of the package for damaged areas.

3. Note the radiation related information stated on the package and other general information and record on a "check-in" form.

4. Test the package for removable contamination using alcohol wipes and the GM detector. If removable contamination exists the wipe test kit should be used to quantify the level of contamination.

5. Open the package and verify that the contents agree in name and quantity with the packing slip.

6. Test the surface of the shielded vial containing the sealed source for removable contamination.

7. If no contamination exists, the packaging can be discarded only after all radioactive labels are removed or crossed out. If contamination exists, the packaging should be sealed in a plastic bag and stored behind protective lead shielding. Again, the amount of contamination should be quantified using the wipe test kit. If removable contamination in excess of 0.01 microcuries (22,000dpm) per 100 square centimeters on the surface of the package is found, the final delivering carrier and the NRC should immediately be notified.

8. Remove the adhesive label which states the initial activity, shipment number, etc. and affix to a receipt form. In some cases it may be impossible to remove the label; in this case, be certain that all the label information is copied onto a receipt form.

9. Monitor the radiation field around the shielded source vial. If the wipe test is negative, the source can be installed in the scanner or temporally stored in a sealed source containment area.

10. Using remote handling devices and adequate shielding open the shielded vial and leak test the source. The wipe test kits should be used at this point.

11. Immediately process the wipe test kit. Wait for results before using the sealed source. Depending on the State Regulations and interpretation of 10CFR35.14(5)(i) a wipe test may not be required if the supplier of the source had a wipe test within the past 6 months and supplied a copy with the shipment.

12. Record all pertinent information on a receipt form.

B.3 Routine Radiation Survey

The term "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions. When appropriate, such evaluation includes a physical survey of the location of materials and equipment, and measurements of levels of radiation or concentrations of radioactive material present. The following situations should necessitate a survey:

1. Incomingand outgoing shipments of byproduct material,
2. Contamination of equipment due to leakage of sealed sources,
3. Sealed source leak testing,
4. Emergency procedures,
5. Routine quality control procedures.

During a survey systematic measurements must be made to determine the following: (1) dose rate,(2) surface contamination, (3) atmospheric contamination, and (4) presence of an unknown radiation source.

A routine survey should be conducted monthly. Records and the results of surveys and monitoring must be preserved for two years after completion of the survey except that the following records shall be maintained until the Radiation Authority (ie., NRC) authorizes their disposal when they pertain to: (1) records of the results used to determine compliance with regulations, (2) in the absence of personnel monitoring data, records of the results of surveys to determined external radiation doses, and (3) evaluation of the release of radioactive effluents to the environment.

B.4 Leak testing

The radiation sources used in bone mineral analyzers are permanently sealed in metal capsules. Before being shipped from the supplier, all such sources must pass inspection for freedom from surface contamination and leakage. Either during transport from the supplier or in the course of time, however, the capsule may develop faults through which the radioactive source material may escape. Although the possiblity of source leakage is remote, each sealed source must be periodically tested for surface contamination and leakage. The NRC device registration allows LUNAR analyzers to contain sources which are leakage tested on an annual basis but we recommend a test interval of 6 month intervals.

The sealed source capsules are inside brass holder. The brass source holder must be removed from the scanner (see section C.1, Source changes) to perform a wipe test. To leak test for surface contamination wipe all exposed surfaces of the brass holder with a piece of filter paper or cotton swab moistened with an appropriate solvent, then measure the activity on the paper or the swab. The source is free of contamination if the activity is less than 0.005 uCi.

The wipe testing must be performed only by individuals who are experienced radiation users. The radiation level at the surface of the brass holder for a new source of Gd-153 is 75 mR/hr. Wipe testing must be performed expeditiously with the source holder directed away from personnel. The radiation levels at the surface of a new I-125 source are much lower, less than 0.1 mR/hr.

Several commercial companies supply wipe test kits that aid in fulfilling this requirement. Follow the directs supplied with the wipe test kit.

B.5 Controlled Area

All radioactive material must be used in a controlled area. This is achieved by labelling the entry into the bone scanning room and noting that access is limited to authorized individuals. If the bone scanning room is a sub-area of a larger controlled space, then the access will be limited at the major entry. The sign must state;

CAUTION RATIATION AREA

and

CAUTION RADIOACTIVE MATERIALS.

There must also be a noticed posted in the area for workers to contact the RSO in case of an emergency, the appropriate location and telephone numbers of State Agency or regional NRC office and location of license and radiation regulation.

B.6 Personnal Monitors

All individuals who work in a controlled area must be monitor for their radiation exposure. This is the familiar film badge dosimeters that are available from several suppliers. These badges are read monthly and the operators radiation exposures are reported.

B.7 Source Disposal/Shipping

Expended sources can be returned to the original supplier; i.e., I-125 sources to AECL in Canada and Gd-153 sources to Gulf Nuclear in Webster, Texas. These manufacturers can provide disposal information. The following is a suggested method for source disposal. These sources can be stored until the total activity is less than 70 mCi for I-125 (6 months) or 200 mCi for Gd-153 (20 months). Several sources can be shipped at one time but the total activity for I-125 must not exceed 70 mCi or 200 mCi for Gd-153. Many carriers will not ship restricted material. However, a depleted source is not considered restricted and can be sent. The shipping form should state "depleted sealed source for recycling" . A statement similar to the following should be included along with the results of the most recent wipe test:

> This shipment conforms to the conditions and limitations specified in 49-CFR-173.421 for excepted radioactive material in limited quantity, n.o.s. UN2910. It contains ____ sealed source(s) of I-125 (Gd-153) radionuclide(s) with an activity of _____ mCi as of _____.

_____
Radiation Safety Officer

The following information will be of assistance when shipping non-exempt sources. The shipper's responsibilities include that where containers are supplied by the shipper, the shipper shall be responsible for determining that shipments are made in containers which have been constructed or assembled with all parts or fittings in their proper place, and marked to show the DOT or ICC specification number and authorized gross weight, e.g., DOT15A-100 (49CFR173.24(c)(1)). See Section B.2.a for package specifications.

Each shipper offering radioactive materials for transportation must provide shipping papers, to include (49CFR173.427(a)(5)):

1. The Transport Group or Groups of the radioactive material, if in normal form;

2. The name of the radionuclides and a description of their physical and chemical form, if the material is in normal form;

3. The activity of the radioactive material in Curies;

4. The type of label applied to the package, i.e., Radioactive White-I, Radioactive Yellow-II, or Radioactive Yellow-III.

5. If the quantity of radioactivity is below levels stated by NRC (10CFR71) and DOT (49CFR170-189) then the category of exempt material applies and no label is required.

Each shipper offering any dangerous article for shipment via air, highway, or rail carriers must show on the shipping papers the following certificate signed by the shipper (14CFR102.2; 49CFR173.430, 174.511, 175.654, 176.704a and 177.819):

> "This is to certify that the above named articles are properly classified, described, packaged, marked and labelled, are in proper condition for transportation, according to the applicable regulations of the Department of Transportation (or Federal Aviation Administration)."

Before the actual shipment the RSO should notify the receiving party ;of the estimated time of arrival of the shipment. The shipment must include "shipping papers" that include all the required information about the source.

C. Routine Health Physics Services

C.1 Source Changes

WARNING: Only individuals trained in the principles of radiation safety and protection and the device specific radiation requirements of LUNAR scanners should conduct these procedures.

C.1.a Gd-153 Source Changes

The source is encapsulated in a metal cylinder, approximately 1 inch in length and 1/8 inch diameter. This metal capsule is inside a lead-lined brass source holder (Fig. 1). For all phases of operation, the capsule need not be removed for the source holder. During a source exhcange the entire source holder is returned. Operator exposure is minimized by never removing the capsule from the holder.

All the following steps should be performed without tools. Use of tools may cause damage to the equipment.

Procedure

1. Remove pad and the lucite insert from the table.
2. Use OPTION 5 (Static Counter, ref. User Manual) of the DP3 Spine software to position the arm and source at the center of the window.
3. Place a lead source holder cap onto the source collimator (Fig. 2)
4. Use the "shutter open" command of OPTION 5 to access the source holder/collimator assembly. Alternatively, the shutter may be manually opened. Be careful to keep hands and other body parts clear of the actual radiation beam. If the source is opened manually, do not force the shutter blade to swing more than 35 degrees; then tape the shutter in this open position during the exchanged.
5. Turn the chuck ring (Fig. 3) counterclockwise until the collimator is loose in the chuck. Do not completely loosen the chuck ring.
6. Pull the source collimator (which will have the source holder attached) out of the chuck. The source holder and collimator can now be handled as an unit.

7. Holding the source holder/collimator upright, as positioned in the scanner, unscrew the source holder from the source collimator. Put the lead cap on the source holder.

   CAUTION: RADIATION PRESENT! After the collimator is removed a broad beam of radiation projects from the top of the source holder.

8. Exchange the spent source for the new source. Place the lead cap from the source holder onto the collimator. Tread the source holder onto the base of the collimator. Do not force the collimator onto the source holder or it may cross-tread. The source holder/collimator can now be handled as an unit.

9. Slide the source holder/collimator into the source chuck (Fig. 3) so that the pin on the bottem fits into the notch on the source chuck. The collimator should rest on the top of the chuck, not the chuck ring.

10. Close the shutter by using "shutter close" command of OPTION 5 or remove any tape used to hold open the shutter.

11. Verify that the shutter blade moves freely in and out of the source collimator. If necessary, adjust the location of the collimator to allow free motion.

12. Turn the chuck ring clockwise until the collimator is held firmly in the chuck.

13. Remove the lead cap from the top of the collimator.

    CAUTION: A narrow beam of radiation is now projected upward from the collimator aperture.

14. Replace the lucite insert and patient pad.

15. Monitor radiation levels around the table to insure operator safety.

16. Perform Standard Scan and QA procedure to verify proper operation.

C.1.b I-125 or Am-241 Source Changes

The I-125 source is encapsulated in a metal cylinder, 10 mm in length and 3 mm diameter. This metal capsule fits inside the brass source holder, SRC-0100-1 (Fig. 4). For all phases of operation, the capsule need not be removed for the source holder.

During a source exchange, the entire source holder is returned. Operator exposure is minimized by never removing the capsule from the holder.

When available, the Am-241 source capsule will be encapsulated in a metal cylinder similar to the I-125 source holder. Due to the long half-live Am-241, no source exchanges will be necessary. The source installation is very similar to the I-125 source.

All the following steps should be performed without tools. Use of tools may cause damage to the equipment.

Procedure

1. Turn off the SP2 scanner and unplug the power cord.

2. Unlock the scanner top (Fig 5) and remove from scanner with care to avoid bumping the detector.

3. The shutter may be manually opened (Fig 6). Be careful to keep hands and other body parts clear of the actual radiation beam. Do not force the shutter blade to swing more than 35 degrees; then tape the shutter in this open position during the exchanged.

4. Turn the source holder assembly (Fig 6) counterclockwise and remove from scanner.Be careful to keep hands and other body parts clear of the actual radiation beam.

5. Holding the source holder assembly upright, as positioned in the scanner, unscrew the source arbor from the source holder. Put the lead cap on the source holder.

   CAUTION: RADIATION PRESENT! After the arbor is removed a broad beam of radiation projects from the top of the source holder.

6. Exchange the spent source for the new source. Place the lead cap from the new source holder onto the old source. Follow standard procedures for source disposal. If a new source is not to be installed, screw the arbor back into place to avoid loss.

7. Screw source holder into arbor.

8. Turn source holder assembly clockwise into scanner and be sure it is properly seated. Verify that the shutter blade can swing freely over the arbor.

CAUTION: A narrow beam of radiation is now projected upward from the collimator aperture.

9. Replace the scanner top and lock into position. Plug in the power cord and turn on the system.

10. Monitor radiation levels around the table to insure operator safety.

11. Perform Standard Scan and QA procedure to verify proper operation.

If Atomic Energy of Canada Limited (AECL) sources C235 are used in AECL holder C236, then an additional source collimator is used in the arbor. This can be inserted in the arbor prior to insertion of the source holder. Use of this additional collimator reduces the beam size at the table thereby lowering radiation exposure and scattered radiation. The SRC-0100-1 source holder does not require the extra collimator since the source itself provides sufficient collimation.

C.2 Source Indicator Light

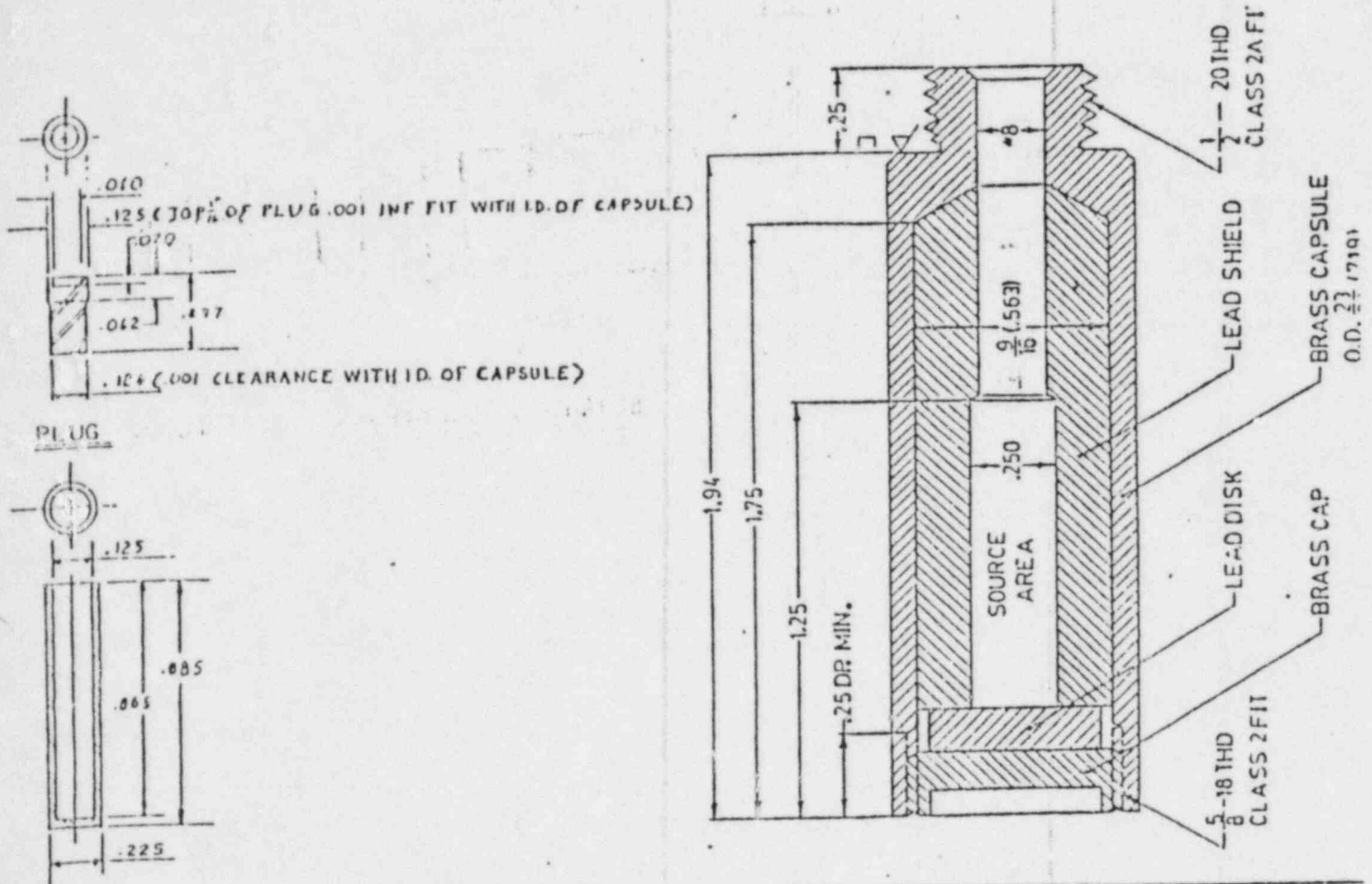
All LUNAR scanner are equipped with a red illuminated light that indicates when the shutter mechanism opens and effectively open the source. When the source is on the computer always indicates this to the operator by a continous message on the screen. The operation of the source light is checked daily by the operator during the STANDARD SCAN and QA.

C.3 Source Shutter Mechanism

The radioactive sources in all LUNAR scanner are effectively turned on/off by means of a rotary solenoid that moves a lead block in/out of the radiation beam. The operation of this shutter is verified daily by the computer during the STANDARD SCAN and QA.

The normal position of the solenoid is closed so that in the event of power failure the source will be shut off.

FIGURE 1
Source Capsule and Holder for 153-Gd Capsule



ODEL GD-1

NOTE:—CAPSULE CAN BE EITHER 17-4PH S.S. OR 2024-T4 ALUMINUM

REVISIONS			GULF NUCLEAR, INC.		
NO.	DATE	BY	GADOLINIUM CAPSULE		
1			DRAWN BY FGI	SCALE NONE	MATERIAL 17-4PH SS
2			CHK'D	DATE 4-2-77	DRAWING NO. A-120
3			TRACED	APP'D	
4					
5					

LUNAR RADIATION CORP. of MADISON, WISCONSIN		
TITLE GADOLINIUM 153 SOURCE HOLDER		
PART#	MATERIAL BRASS & LEAD	
FOR ASSEMBLY	TOLERANCES (unless otherwise specified) .00 ± .01 .000 ± .001	
SCALE 4:1	DIMENSIONS ARE IN INCHES	BREAK ALL EDGES AND CORNERS
DESIGNED date	DRAFTSMAN date	CHECKED date
ENGINEER 7/82	B. BUSCH 2/82	APPROVED date

CONTROL NO. 80904

FIGURE 2
Gd-153 Source Collimator/Holder Assembly
for DP3 Scanner

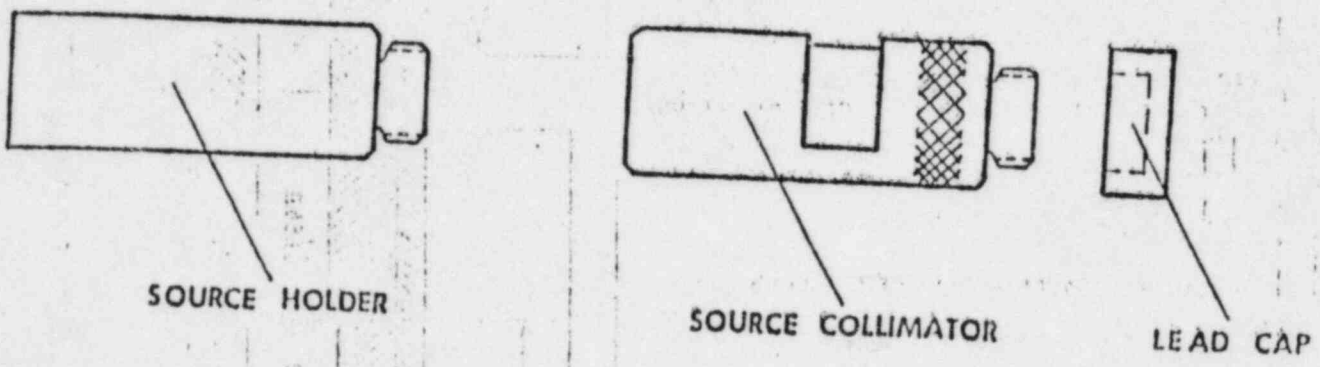
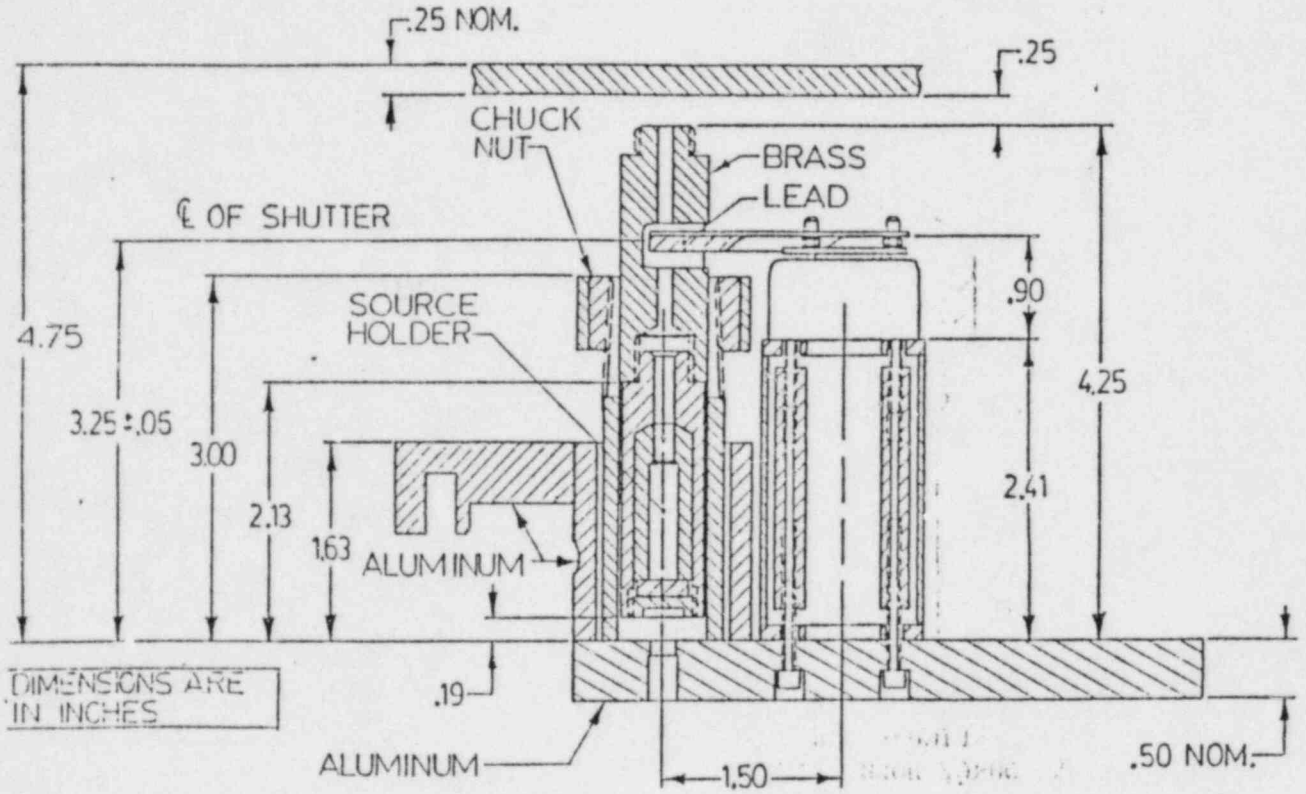


FIGURE 3
Side View of Transverse Carriage of DP3 Scanner



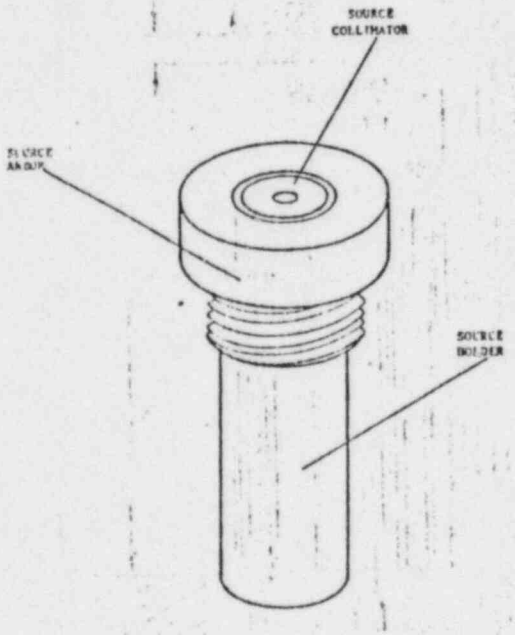


FIGURE 4
I-125 SOURCE HOLDER ASSEMBLY
FOR SP2 SCANNER

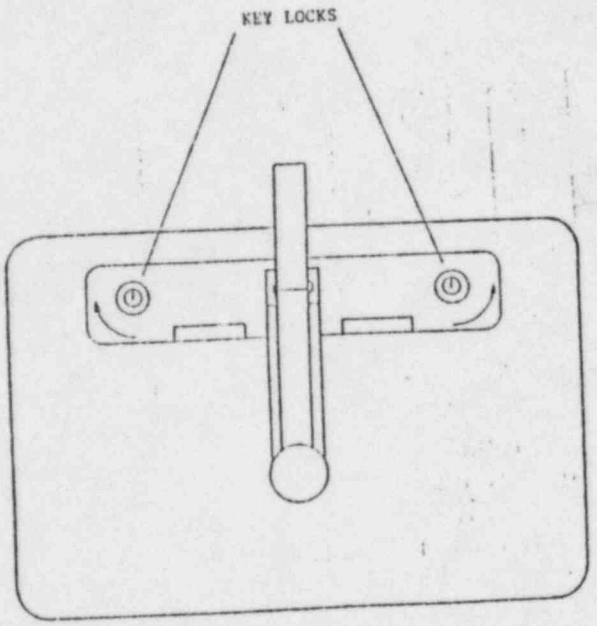


FIGURE 5
UNLOCKING SP2 TOP

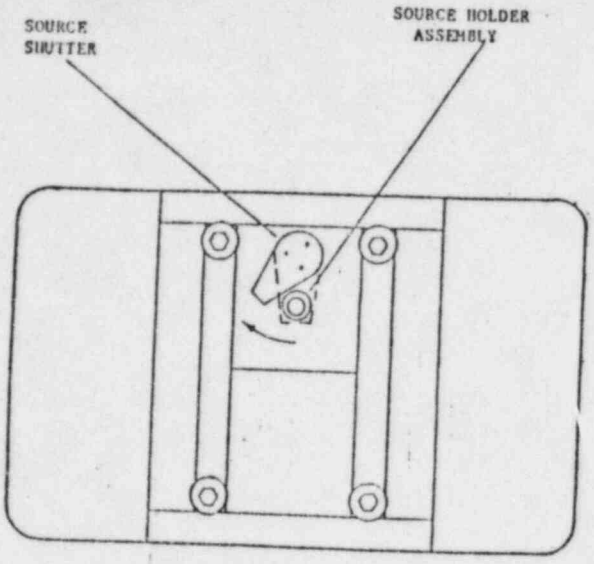


FIGURE 6
SOURCE LOCATION & REMOVAL
NOTE: "DASHED" lines refer to
shutter in "occluded" position.

SPECIAL PROCEDURES FOR PATIENTS TREATED WITH IRIDIUM 192 WIRES

a. You must describe the area where Ir-192 sources will be stored, including (1) placement and thickness of shielding (2) proximity of the storage area to any unrestricted areas. This condition is best satisfied with a sketch which should include the radiation levels on all sides of the storage safe.(see attachment)

b. Special precautions to be used while handling sealed sources.

1. All Iridium wires are stored in shipping pig or labeled lead safe. When fully loaded the maximum radiation level at 5 cm. from the surface of the safe is 120 mr/hr.

2. Any manipulation of the sources prior to use is done within a shielded area with forceps. Forceps and scissors will be monitored for removable contamination, and decontamination if necessary.

3. All sources are contained in a shielded source carrier before leaving the storage area.

4. Iridium sources will be transported to the treatment area by personnel trained in the proper handling of radioactivity.

5. The Iridium sources will be administered or after loaded by the radiotherapist.

c. All personnel handling Iridium wires will be supplied with TLD ring badges to determine the radiation dose to their extremities.

d. Describe the equipment and shielding available for transporting sources from storage sites to place of use. A sketch of the device with thickness of lead and radiation levels at 5 cm. will satisfy this requirement. Often a manufacturers brochure is adequate.(see attachment)

e. The following inventory procedure will be kept for maintaining source accountability at all times.

CONTROL NO. 80904

INVENTORY PROCEDURE

1. A sign in sign out procedure will be kept for all Iridium wires.

2. When Iridium wires are received by the institution the number of sources received, their strength, and the calibration date is recorded in the brachytherapy inventory log.

3. Prior to use for treatment, the number of wires placed in the safe for transport to surgery or the treatment area will be recorded on form RS-100, (copy attached), or equivalent form.

4. At such time that sources are returned to the storage area, whether unused for a specific treatment or at the completion of treatment, the number of sources (wires), the strength, and the date will be recorded on RS-100, or equivalent form.

5. Always initial or sign the inventory form when checking out or checking in sources.

6. Render comments. Please indicate whether sources returned are returned prior to treatment or after treatment is completed.

f. Surveys will be performed during the course of treatment and at the conclusion of treatment. The patient and room will be surveyed with a GM-type survey meter at the end of treatment and before dismissal. The dismissal survey will include a source count and will be adequate to determine that all temporary implant sources have been removed from the patient and from all areas that the patient occupied.

g. Instructions for nursing care of patients who are treated with Iridium wires will be in accordance with our current procedure for sealed source therapy (copies attached).

RS-100

IRIDIUM WIRE TRANSFER RECORD

Institution _____

Patient's Name _____ Hosp. No. _____ Room No. _____

DESCRIPTION OF SOURCES DELIVERED TO THE TREATMENT AREA

No. Carriers	Type	Sources Per Carrier	Active Length	Condition/Remarks

Checked, recorded above, and delivered by _____
(Signature and Title)

Checked against description, and received by _____
(Signature and Title)

Date delivered _____ Time _____ (AM.PM.)

DESCRIPTION OF SOURCES RETURNED TO THE STORAGE AREA

No. Carriers	Type	Sources Per Carrier	Active Length	Condition/Remarks

Checked, recorded above, and released by _____
(Signature and Title)

Checked against description, and received by _____
(Signature and Title)

Date returned _____ Time _____ (AM.PM.)

DISMISSAL SURVEY

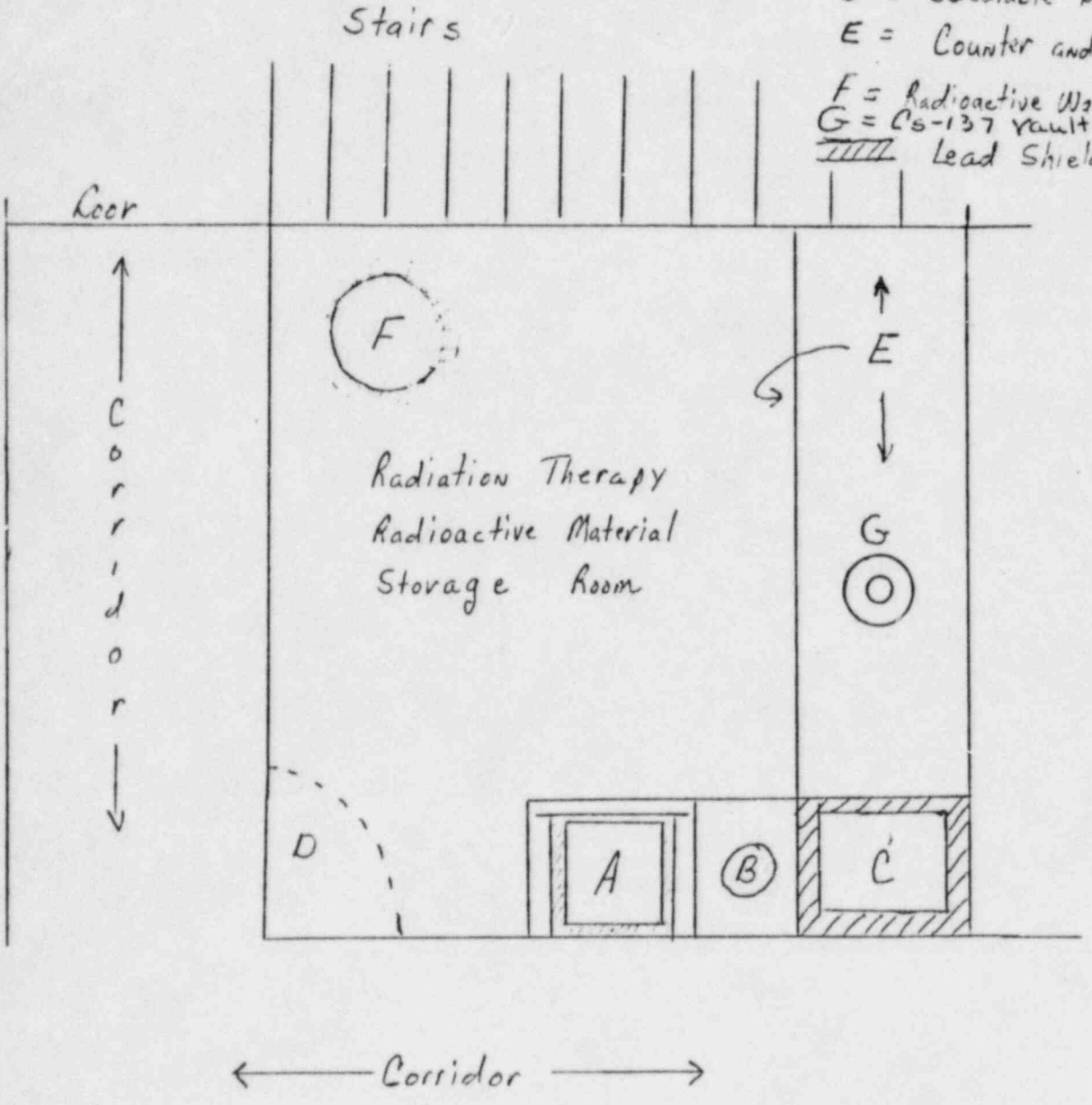
Position	Radiation Level	Date	Signed	Comments
Patient				
Area (Room)				
Other				

CONTROL NO. 80904

Rockford Memorial Hospital
Rockford, Illinois
License No. 12-02530-03

Scale: One Inch ≈ 2 feet

Key: A = Cs-137 Vault (3m)
B = Sr-90 Source Storage
C = Radioactive Material Storage
D = Securable Door
E = Counter and Storage Cabinets
F = Radioactive Waste Container (I-131 Decay Barrel)
G = Cs-137 Vault (Nuc. Assoc.)
Lead Shielding



Item 11

(2/85)

Description of Shielded Carrier

Mfr: Radium Chemical Co.

Model: "Ernst" Carrier, Stainless Steel

Lead Lined - Lid + Bottom = 1" thick

Sides - .8" - .87" thick

External Dimensions: 8" L x 4" D x 4¼" H

Internal Dimensions: 6.3" L x 2" D x 2" H

CONTROL NO. 80904

PRECAUTION SHEET

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH BRACHYTHERAPY SOURCES

Patient's Name: _____

Room Number: _____ Physician's Name: _____

Isotope and Activity: _____

Date and Time of Administration: _____

Date and Time Sources Are To Be Removed: _____ Isotope: _____

Exposure Rates in mR/hr

DATE	TIME	BEDSIDE	3 FT.FROM PT.	6 FT. FROM PT.	10 FT. FROM PT.

(Comply with all checked items.)

_____ 1. Wear film or TLD badge.

_____ 2. Wear pocket chambers for supplementary personnel monitoring of individual tasks.

_____ 3. Wear rubber gloves.

_____ 4. Tag the following objects and fill out the tag:

_____ door _____ chart

_____ bed _____ wrist

_____ 5. Place laundry in linen bag and save.

_____ 6. Housekeeping may not enter the room.

_____ 7. Visiting time permitted: _____

_____ 8. Visitors must remain _____ from patient.

_____ 9. Patient may not leave the room.

_____ 10. Patient may not have visitors.

_____ 11. Patient may not have pregnant visitors.

_____ 12. Patient may not have visitors under 18 years of age.

_____ 13. Patient must have a private room.

_____ 14. A dismissal survey must be performed before the patient is discharged.

_____ 15. All items must remain in the room until approved for disposal by the Radiation Safety Officer or his designee.

_____ 16. Contact the Radiation Safety Office when temporary sources (nonpermanent implants) are removed to perform a survey to be sure all sources are removed from the patient, to do a physical source count, and to be sure no sources remain in the room.

_____ 17. Contact the Radiation Safety Office when the patient is discharged to survey the room prior to its assignment to another patient.

_____ 18. Other instructions.

RSO _____

Name On-duty/Off-duty Telephone Numbers

SOURCES INSERTED	INITIALS	SOURCES REMOVED	INITIALS	SOURCES STORED	INITIAL

BRACHYTHERAPY ROOM SURVEY
ROCKFORD MEMORIAL HOSPITAL

SURVEY DATE: __/__/__ ROOM NUMBER: _____

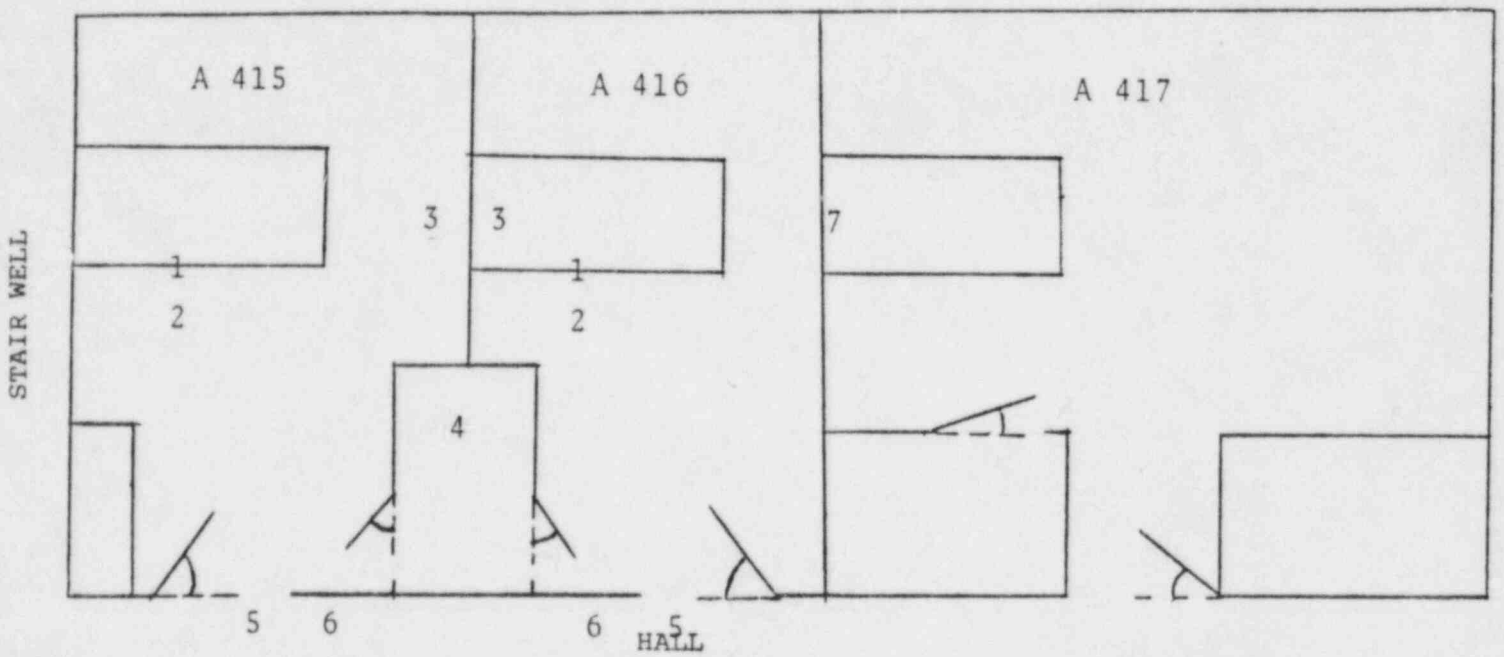
SOURCE TYPE: _____ SOURCE STRENGTH: _____

INSERTED ON: __/__/__ PLANNED REMOVAL: __/__/__

TIME INSERTED: _____ AM/PM REMOVAL TIME: _____ AM/PM

PATIENT NAME: _____ PLANNED HOURS: _____

AREA SURVEY
NORTH-OUTER WALL



LOCATION	READING (mREM/Hr)	LOCATION	READING (mREM/Hr)
1. SIDE OF BED:	_____	5. DOOR-OPEN:	_____
2. 3 FEET FROM PATIENT:	_____	CLOSED:	_____
3. ADJACENT WALL (ROOM ___):	_____	6. HALL:	_____
4. BATH:	_____	7. WEST WALL A417:	_____

CHECK LIST	MPR's	OCCUPANCY FACTORS
Warning on door	Nurse = 100 mREM/Case	Adj. Pt. = 1
Warning on Chart	Adj. Pt. = 100 mREM/Case	Most Others = 1/3 of usual values to account for roughly 8 hr day.
Nurse. Inst. Chart	Visitors = 500 mREM/Case	

SPECIAL INSTRUCTIONS, COMMENTS OR OBSERVED PROBLEMS:

Survey By: _____ Review By: _____

IN CASE OF EMERGENCY CALL: Joel M. Busse, M.D. Ex. 5541

FINAL SURVEY

Date:_____ Time:_____ Surveyer:_____

Survey indicated that no sealed sources remained in patient.

Survey indicated that no significant radiation levels or removable contamination was present.

LOCATION	EXPOSURE RATE	REMOVABLE CONTAMINATION
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Room was decontaminated and all radioactive material removed. Date:_ _____

Comments:_____

_____

_____

CONTROL NO. 80904

iridium 192
W I R E S

Syncor Iridium 192 wires are for use in the treatment of malignant tumors by interstitial or intracavitary radiotherapy (brachytherapy). Each flexible, irradiated platinum-iridium wire is encased in an inert platinum sheath to filter out the beta component. The wires are available as single or double-leg hairpin sources for use with guide gutters or as straight wires up to 50 cm in length.

EASY TO USE
Syncor Iridium 192 wires come in a range of easily managed lengths, so there's no problem with tangling. And, because of their semi-rigid nature, they are easy to form into almost any desired configuration, no matter how intricate. Syncor wires can be conveniently sterilized by either autoclave, gas or aqueous solution.

VERSATILE
Syncor wires are compatible with *all* currently used interstitial implant accessories. There's no special equipment to buy, no extra supplies to stock.

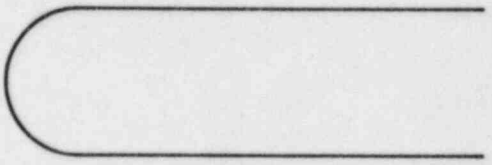
COMPLETE
If you do need accessories, however, Syncor offers the most comprehensive selection, specifically for use with Iridium 192 wires, including deep cavity suturing instruments and surgical quality wire cutting scissors.

SAFE
Each wire is individually packaged in a screw top container enclosed in a lead shield for your protection. Orders for multiple wires of the same activity are packaged together.

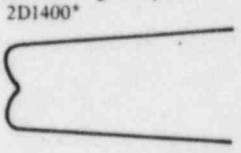
WASTE-FREE
Syncor Iridium 192 wires are usable throughout their entire active life. Since the exact length of wire required can be inserted into the plastic ribbon just prior to treatment, this eliminates the degradation of the plastic ribbon, so no source material is wasted.

UNIFORM QUALITY
Activity in each wire differs by not more than 2% over its entire length. Likewise, the difference in activity between any two wires (or pins) from the same batch is always less than 2%. Radioactive output is consistently within +10%, −0% of the activity ordered. You don't get surprises from Syncor—just uniform quality, time after time. And since each centimeter of wire is calibrated by the European equivalent of NBS, you can depend on the reliability of calibration.

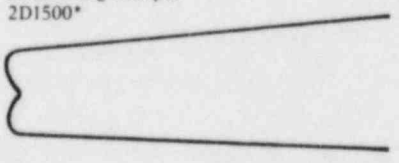
Continuous Wire
2D1100-0.5 mm diam.*
2D1000-0.3 mm diam.



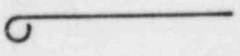
Double-Leg Hairpin
2D1400*



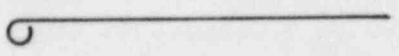
Double-Leg Hairpin
2D1500*



Single-Leg Hairpin
2D1200*



Single-Leg Hairpin
2D1300*



*Actual size

syncor™

SPECIFICATIONS

Each source is irradiated Pt(75%)-Ir(25%) wire in 0.3 or 0.5 mm diameter. The platinum sheath is 0.1 mm thick.

RADIATION

$T_{1/2}$ = 73.83 ± 0.07 days
HVL = 3 mm lead

Gamma energy (MeV):

0.205 (3.3%)	0.316 (83.0%)	0.588 (4.5%)
0.296 (28.7%)	0.468 (47.8%)	0.604 (8.1%)
0.308 (29.7%)	0.484 (3.2%)	0.612 (5.3%)

Average gamma energy = 0.35 MeV
Specific gamma ray constant (RHM) = 4.9 ± 0.2 expressed as $\frac{\text{R-cm}^2}{\text{h-mCi}}$*

CHARACTERISTICS

Product #	Total Length (mm)	Outer Diameter (mm)	Linear Activity (mCi/cm)	Activity* (mg Ra eq/cm)	Linear Exposure Rate (mR/cm at 1 m)
2D1000	140	0.3	1-3	0.6-1.8	0.49-1.47
2D1100	140	0.5	6-10	3.6-6.0	2.94-4.90
2D1200	30	0.5	1-3	0.6-1.8	0.49-1.47
2D1300	50	0.5	1-3	0.6-1.8	0.49-1.47
2D1400	72	0.5	1-3	0.6-1.8	0.49-1.47
2D1500	112	0.5	1-3	0.6-1.8	0.49-1.47

Coiled lengths of up to 50 cm and pre-cut lengths encased in plastic ribbons are available upon request.
*Γ constant ^{192}Ir = 4.9, Γ constant ^{226}Ra = 8.25. All calibrations of ^{192}Ir wires are NBS-traceable.

DELIVERY TIME

Products listed above can be received within 10-14 days after receipt of order. For all other activities, delivery times are given upon request.

SUPPLEMENT

A flexible plastic tube (ciponyl nylon) for loading the wire is available. Please order tubing for wire, product number 2F1620. This tubing can be inserted into a 17 G. needle.

syncor™
Manufactured in France by ORIS, a division of CEA

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