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NRC FORM 313M

(9-81)

10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

02201

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Approved by OMB
3150-0041
Export 9-83

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 Material 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
C.P.U.P.
OB GYN Presbyterian Medical Office Building
Suite 220
51 North 39th Street
Philadelphia PA 19104
TELEPHONE NO.: AREA CODE (215) 662-8798

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (If different from 1.a.) INCLUDE ZIP CODE
SAME AS 1a and
David A. Iddenden, M.D.
Cherry Hill Medical Arts Bldg.
7740 Maple Avenue
Pennsauken, New Jersey 08109

2. PERSON TO CONTACT REGARDING THIS APPLICATION
Stan A. Huber Consultants, Inc.
200 North Cedar Road
New Lenox, IL 60451
TELEPHONE NO.: AREA CODE (815) 485-6161

3. THIS IS AN APPLICATION FOR: (Check appropriate item)
a. ☒ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
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.)
David Iddenden, M.D.
Galen Rogers, M.D.

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.)
David Iddenden, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES			IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP III			GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		
10 CFR 35.100, SCHEDULE A, GROUP VI					

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

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Iodine-125	Sealed Source AECL Model C324	Nominal 200 mCi per source (+25% to -10%) (Maximum of two (2) sources)	Nuclear Data Model ND1100 Bone Density Scanner "OFFICIAL RECORD COPY" ML10 MAY 30 1985 03898

License Fee Information
on Next Page 3

8507240329 850624
REG1 LIC30
37-20856-01 PDR

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. 1, Date: October 1980.

NOTE: All appendices referenced on this page are based on Regulatory Guide 10.8, Rev. 1, and are attached to this application. Some appendices have been slightly modified to reduce the regulatory burden.

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

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	FILM	NOT REQUIRED	
	TLD		
	OTHER (Specify)		
b. FINGER	FILM		
	TLD		
	OTHER (Specify)		
c. WRIST	FILM		
	TLD		
	OTHER (Specify)		

d. OTHER (Specify)

RECEIVED BY LFMB

Date 6/12/85

Leg. June Pg 4 - I

By Jacques

Orig. To LFMB

Action Compl 6/18/85

Applicant 1114

Check No. 1114

Amount/Fee Category \$580-7C

Type of Fee Application

Date Check Rec'd 5/30/85

Received By Jacques

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL		
NAME OF HOSPITAL NOT APPLICABLE		b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.
MAILING ADDRESS		c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.
CITY	STATE ZIP CODE	

26. CERTIFICATE

(This item must be completed by applicant)

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

a. LICENSE FEE REQUIRED (See Section 170.31, 10 CFR 170)	b. APPLICANT OR CERTIFYING OFFICIAL (Signature) <u>D. Iddenden</u>
	(1) NAME (Type of Print) David Iddenden, M.D.
(1) LICENSE FEE CATEGORY: <u>7C</u>	(2) TITLE Director
(2) LICENSE FEE ENCLOSED: \$ <u>580.00</u>	c. DATE May 20, 1985

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on Form NRC-313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 453346 (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.

TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

David A. Iddenden, M.D.

**2. STATE OR TERRITORY IN
WHICH LICENSED TO
PRACTICE MEDICINE**

PA and NJ

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
OB-GYN	OB-GYN	June 1981, England December 1983 USA

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Nuclear Data, Inc. Schaumburg, IL May 8, 1985	3	
b. RADIATION PROTECTION	" " "	2	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY	" " "	3	
e. RADIOPHARMACEUTICAL CHEMISTRY	(See attached Training Certificate)		

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I-125	200 mCi	Nuclear Data, Inc	4 hours	Machine Demo Operator Training

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1 NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER Galen Rogers	2 STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE PA and NJ
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3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
OB-GYN (eligible)	OB-GYN	Written exam passed June 1983

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Nuclear Data, Inc. Schaumburg, IL May 8, 1985	3	
b. RADIATION PROTECTION	" " " "	2	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY	" " " "	3	
e. RADIOPHARMACEUTICAL CHEMISTRY	(See attached Training Certificate)		

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I-125	200 mCi	Nuclear Data, Inc Schaumburg, IL	4 hours	Machine Demo Operator Training

STAN A. HUBER CONSULTANTS, INC. 200 NORTH CEDAR ROAD NEW LENOX, IL 60451 (815) 485-6161

CERTIFICATE OF TRAINING

This is to certify that David Iddenden, M.D., M.R.C.O.G. has successfully completed training in accordance with the Nuclear Regulatory Commission's (NRC) Policy and Guidance Directive FC83-24, "Licensing the Human Use of the Lixiscope and Bone Mineral Analyzer", dated November 10, 1983.

The training included all topics listed in the enclosure with that Directive, entitled "Recommended Medical Users Training for Lixiscope and Bone Mineral Analyzer Diagnostic Devices", specified as Group A - Basic Radiation Physics and Instrumentation (three (3) hours); Group B - Radiation Biology (three (3) hours); and Group C - Radiation Protection (two (2) hours).

This training was completed on May 8, 1985.

In addition, the above certified individual participated in a demonstration of the proper loading and unloading of the shielded source holder (source exchange procedure) of the bone mineral analyzer device which will be used by the licensee. This demonstration was conducted by Stan Huber, using a dummy (non-radioactive) source holder, at Nuclear Data, Incorporated facilities in Schaumburg, Illinois. This training was completed on May 8, 1985.

A copy of this certificate is to be provided to the NRC or Agreement State as proof the trainee has the necessary training and experience to make a specific application for a Byproduct (Radioactive) Material License to possess and use a bone mineral analyzer.

This document was prepared in conformity with Title 10, Code of Federal Regulations, and the NRC Policy and Guidance Directive FC83-24. All information contained herein is true and correct to the best of our knowledge and belief.

Certified by: Stan A. Huber Consultants, Inc. Instructor: Stan A. Huber

Under License : NRC License #12-17503-01

Signature: Stan A. Huber

Date: May 8, 1985



STAN A. HUBER CONSULTANTS, INC. 200 NORTH CEDAR ROAD NEW LENOX, IL 60451 (815) 485-6161

CERTIFICATE OF TRAINING

This is to certify that Galen Rogers, M.D. has successfully completed training in accordance with the Nuclear Regulatory Commission's (NRC) Policy and Guidance Directive FC83-24, "Licensing the Human Use of the Lixiscope and Bone Mineral Analyzer", dated November 10, 1983.

The training included all topics listed in the enclosure with that Directive, entitled "Recommended Medical Users Training for Lixiscope and Bone Mineral Analyzer Diagnostic Devices", specified as Group A - Basic Radiation Physics and Instrumentation (three (3) hours); Group B - Radiation Biology (three (3) hours); and Group C - Radiation Protection (two (2) hours).

This training was completed on May 8, 1985.

In addition, the above certified individual participated in a demonstration of the proper loading and unloading of the shielded source holder (source exchange procedure) of the bone mineral analyzer device which will be used by the licensee. This demonstration was conducted by Stan Huber, using a dummy (non-radioactive) source holder, at Nuclear Data, Incorporated facilities in Schaumburg, Illinois. This training was completed on May 8, 1985.

A copy of this certificate is to be provided to the NRC or Agreement State as proof the trainee has the necessary training and experience to make a specific application for a Byproduct (Radioactive) Material License to possess and use a bone mineral analyzer.

This document was prepared in conformity with Title 10, Code of Federal Regulations, and the NRC Policy and Guidance Directive FC83-24. All information contained herein is true and correct to the best of our knowledge and belief.

Certified by: Stan A. Huber Consultants, Inc. Instructor: Stan A. Huber

Under License : NRC License #12-17503-01 Signature: *Stan A. Huber*

Date: May 8, 1985

STAN A. HUBER CONSULTANTS, INC. □ 200 NORTH CEDAR ROAD □ NEW LENOX, IL 60451 □ (815) 485-6161

CERTIFICATE OF TRAINING

This is to certify that Mary Ann Saxman, R.N. has successfully completed training in accordance with the Nuclear Regulatory Commission's (NRC) Policy and Guidance Directive FC83-24, "Licensing the Human Use of the Lixiscope and Bone Mineral Analyzer", dated November 10, 1983.

The training included all topics listed in the enclosure with that Directive, entitled "Recommended Medical Users Training for Lixiscope and Bone Mineral Analyzer Diagnostic Devices", specified as Group A - Basic Radiation Physics and Instrumentation (three (3) hours); Group B - Radiation Biology (three (3) hours); and Group C - Radiation Protection (two (2) hours).

This training was completed on May 8, 1985.

In addition, the above certified individual participated in a demonstration of the proper loading and unloading of the shielded source holder (source exchange procedure) of the bone mineral analyzer device which will be used by the licensee. This demonstration was conducted by Stan Huber, using a dummy (non-radioactive) source holder, at Nuclear Data, Incorporated facilities in Schaumburg, Illinois. This training was completed on May 8, 1985.

A copy of this certificate is to be provided to the NRC or Agreement State as proof the trainee has the necessary training and experience to make a specific application for a Byproduct (Radioactive) Material License to possess and use a bone mineral analyzer.

This document was prepared in conformity with Title 10, Code of Federal Regulations, and the NRC Policy and Guidance Directive FC83-24. All information contained herein is true and correct to the best of our knowledge and belief.

Certified by: Stan A. Huber Consultants, Inc. Instructor: Stan Huber

Under License : NRC License #12-17503-01 Signature: Stan Huber

Date: 8 May 1985

Suite 320 - Medical Office Bldg
Presbyterian-University of
Pennsylvania Medical Center
Philadelphia, PA

Exam Room #2 - 7.6' x 9.0'

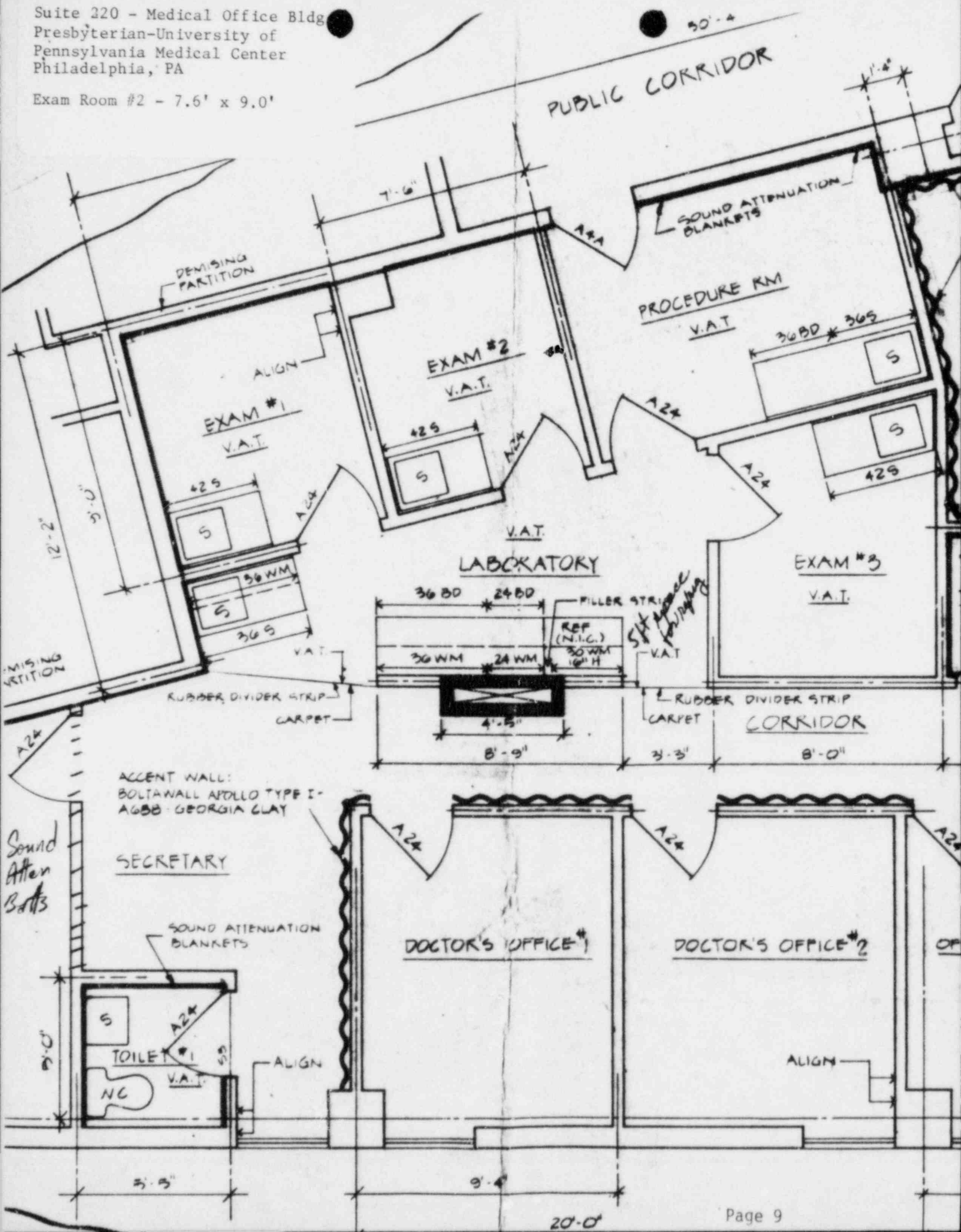
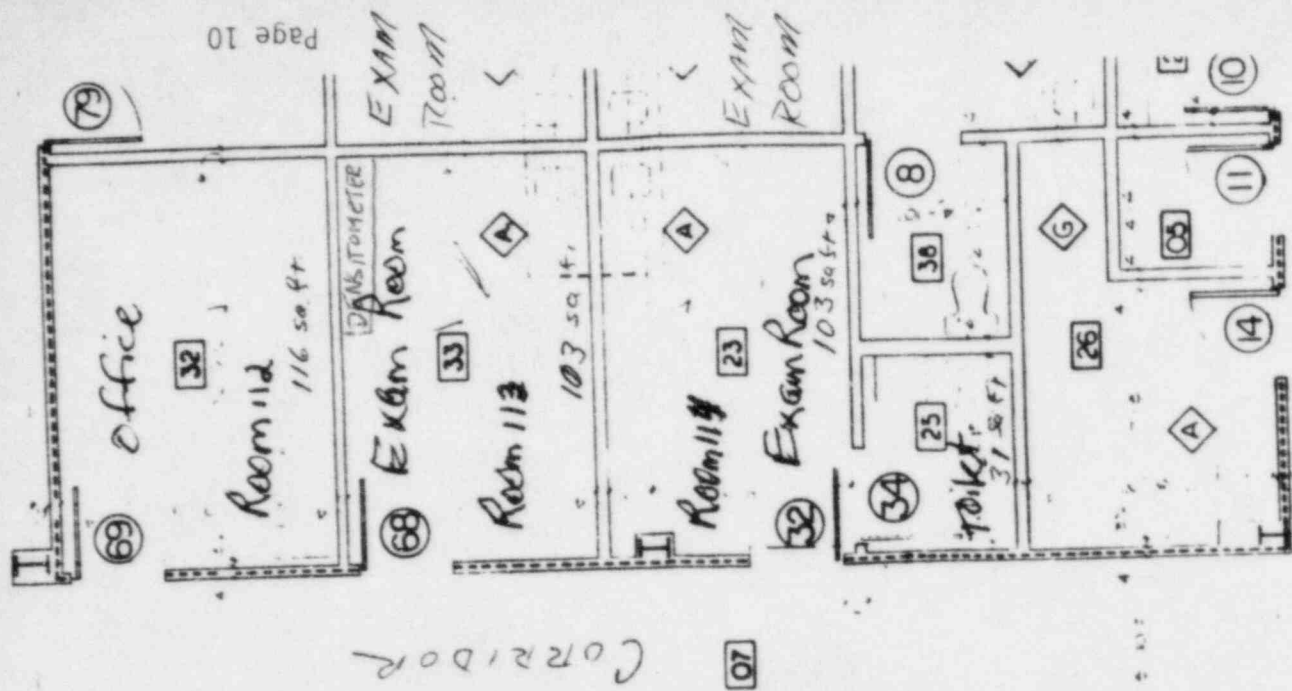


Exhibit A

Cherry Hill Medical Arts Building
7740 Maple Avenue
Pennsauken, NJ
Room 133 - 103 sq ft



SUPPLEMENTAL INFORMATION REGARDING BONE DENSITOMETER TRANSPORT

1. David Iddenden, M.D.; Galen Rogers, M.D.; or Mary Saxman, R.N. whose training certificates are enclosed with this application, may transport the bone density scanner by personal car or van from their Philadelphia, PA office to their Pennsauken, NJ office and return. The distance between these offices is about twenty miles.
2. The DOT shipping papers received from the supplier will be carried (on the drivers seat) with the bone density scanner during such transport, to identify the shipment. We will also carry a transport paper indicating the origin and destination of the shipment.
3. The bone density scanner will be secured (braced and tied) in the vehicle to prevent any shifting of the scanner during transport.
4. The scanner will be attended at all times during transport and will be removed upon arrival at destination, to prevent loss or theft.
5. The facility sketches of the bone density scanner room to be used at each of the two office locations are shown in this application. These rooms are either attended by our personnel or locked when not in use, to prevent unauthorized access.

Instrumentation

One (1) Nuclear Data Model ND1100 Bone Density Scanner

A survey meter is considered unnecessary, since the supplier performs a radiation survey and performs leak testing on the sealed source at time of shipment. These shipping and leak test certificates are filed at our facility.

In the event of a damaged shipment, loss or theft, we would arrange to have appropriate survey and monitoring as defined in Item 14 "Receiving and Opening Procedures" of this application.

REF: NRC 313 M - ITEM 10

Calibration of Instruments

We will perform the calibration of the Nuclear Data Bone Density Scanner in accordance with the method and frequency indicated in the supplier operating and user manuals.

Any survey meters or other radiation detection instruments that would be brought into our facility for special projects, such as evaluating a damaged shipment, would be checked as having proper calibration and operation certification as defined in NRC Regulatory Guide 10.8, October 1980, Appendix D.

Facilities and Storage (Security) Description

A detailed facility sketch is attached to this application.

- a) Only I and my office staff have keys to the rooms shown on the facility sketch submitted with my license application.
- b) Doors to our office suite, or at least to the bone scanner room, will be kept locked when not in use, to prevent unauthorized access.
- c) An alternate security procedure we may use is to lock the bone scanner or any source exchange shipments, awaiting pick-up or installation, in a secure storage cabinet or closet in our office suite.

REF: NRC 313M - ITEM 12

Personnel Training Program

- a) Training documentation and certification is attached to this application for each user.
- b) Further description of our Personnel Training Program is outlined in:
 Item 14
 Item 15 (d)
 Item 23 (a) (b) (c) (d)
 included in this application.

REF: NRC 313M - ITEM 13

Procedures for Ordering and Receiving Radioactive Material

- a) A copy of the appropriate NRC license must accompany the order to the supplier for a new source. Upon receipt of the new source, the old source will immediately be returned to the AECL, per DOT CFR 173.422, per supplier shipping instructions. AECL is the supplier of the I-125 sealed sources loaded into the Nuclear Data shielded source holders.
- b) Source will be shipped in a Type A container, along with the following statement on the packing slip inside the package:
 "This package conforms to conditions and limitations specified in 49.CFR 173.422 for Radioactive Material, Instruction and Articles, UN 2911".
- c) Shipment receipt and handling procedures are outlined in Items 14 and 15 of this application.

Shipment Receiving and Opening Procedures

- a) Only a licensed user, or technologist we have trained, will receive and/or open bone scanner source shipments.
- b) The person opening the package will check that the packing list agrees with the standard source order and that the supplier has provided a leak test certificate. If not, the Radiation Safety Officer (R.S.O.) on our license will be notified to contact the supplier. The shipment receiving and return records and leak test certificates are to be maintained on file for inspections.
- c) In the event any damage is noted on the interior container of the shipment, or any unusual condition exists, the person opening the package will immediately notify the R.S.O.
- d) Actions the R.S.O. would likely take with damaged shipments include isolation of the package to a secured storage cabinet, shielding the source with lead containers, and instructing personnel to remain out of the storage area until the situation is resolved. Resolving the problem of any exposure potential would include calling the manufacturer, supplier, or nuclear consultant for counsel, supplying appropriate monitoring devices and/or leak test analysis before the source is further handled or put into use. An incident of this type would be extremely rare, and the regulatory agencies would only need to be notified if an exposure problem is indeed found to exist.
- e) See attached "Procedures for Safely Opening Packages Containing Shielded I-125 Sources for Bone Densitometers" for detailed package opening procedures

**Procedures for Safely Opening Packages Containing
Shielded I-125 Sources for Bone Densitometers**

1. Visually inspect package for any sign of damage. If damage is noted, stop procedure and notify Radiation Safety Officer (R.S.O.)
2. The exposure rate at package surface was checked by the supplier as being less than 10mr/hr at three feet and less than 200mr/hr at package surface or the package could not have legally been shipped. Since only one low energy sealed source, contained in a lead shielded source holder is received at one time, the usual precautions for a variety of different radionuclide shipments are not applicable unless the package is damaged. The fact that the shipment (source holder) does indeed contain no more than 200 mCi of I-125 is confirmed by loading the source holder into the bone scanner source holder head and obtaining a read-out of the activity. If the activity read-out would vary from the order and supplier specifications, the R.S.O. would call the supplier for instructions.
3. The source holder is to be routinely handled by use of remote handling devices such as tongs or forceps. Gloves would be worn if necessary for any reason to handle the shielded source holder with one's fingers, for as brief a period as absolutely necessary, even though the lead shield results in minimal exposure.
4. Open the outer package (following manufacturer directions, if supplied) and remove packing slip. Open inner package to verify contents (compare order, packing slip, and label on shipment container), and check integrity of final source container (inspecting for any damage or breakage of seals). Check also that the shipment does not exceed possession limits by loading the shielded source holder into the bone scanner source holder head and obtaining a read-out of the activity, after step 5 has been completed.
5. Before loading the shielded source holder into the bone scanner source holder head, check that the supplier has provided a current leak test certificate for the sealed source assembly in the shipment. If the certificate is not with the shipment, call the supplier immediately to verify they have tested the specific sealed source assembly and that they will mail the certificate. The sealed source assembly must not be handled further until this verification is made.
6. After the bone scan source activity has been confirmed and the leak test certification has been verified, the empty package, including packing materials (other than documents), are to be taken to a locked and secure storage cabinet for later use in making the return shipment to the supplier after the source has decayed to an unusable level, in accordance with supplier instructions.
7. In the event a damaged package would be received, the R.S.O. is to be immediately notified. The package will not be opened until the R.S.O. notifies Nuclear Data and AECL of the incident and arrangements are made to immediately deliver an appropriate thin-end window G.M. survey meter (such as a Ludlum model 14-C survey meter or Victoreen Thyac III meter, or equivalent, with thin-window probes), as well as providing appropriately licensed personnel, such as S.A. Huber Consultants, Inc. of New Lenox, Illinois, to handle such a case and provide consultation and documentation assistance.

General Rules for Safe Use of Radioactive Material

- a) Only a licensed user, or appropriately trained and qualified technologist under the supervision of a licensed user, will have access to the source shipments or to operate the bone scanner.
- b) The users will follow the supplier instructions for return shipments; the conditions in this license for receiving and opening shipments, and will follow the manufacturer's operating manual for safely using the bone scanner.
- c) Access to allen wrenches for the source holder, keys, and other security measures or source installation devices will be restricted only to personnel who have been specifically trained in the safe handling of radioactive material and the bone scanner device.
- d) The Radiation Safety Officer (R.S.O.) of the licensee has the ultimate responsibility and authority to assure that all personnel who could have any involvement with radioactive shipments or the bone scanner have been appropriately trained for their tasks. This includes the possibility of any shipment receiving personnel outside the immediate office area, who would be instructed to have the courier immediately take shipments to the licensed office area, as well as instructions to any housekeeping staff not to discard any boxes marked "Caution - Radioactive Materials". Office personnel are instructed to save, in a secured area, empty supplier boxes and labels for later source exchange return shipments to the supplier.
- e) The licensee will not permit anyone, except for patients for medical purposes, to be exposed to the radiation beam of the diagnostic instrument.
- f) The shielded source will be installed in the bone scanner shielded source holder as soon as practical upon receipt of shipment. The shielded source and holder will be left attached to the instrument except for source exchange, to provide maximum security and shielding and minimal potential for any accountability problems.
- g) It is confirmed that I-125 sealed sources will not be handled outside the source holder. The I-125 sealed source will arrive within its lead or brass shielded source holder, which is also called a collimator. The lead (brass) shielded source holder is removed from its shipping container with a forceps or other remote handling device and slipped into the source holder recess in the source holder head of the device. The I-125 source itself is never directly handled.
- h) Nuclear Data, Inc. or other persons specifically authorized to service the bone mineral analyzer will perform all maintenance and repair on the device.
- i) Only individuals who have successfully completed the manufacturer's training course or an approved training course may remove and install sources. The licensed user or staff who have successfully completed the supplier (Nuclear Data) or equivalent licensed training course and supplier demonstration, may operate the bone density device in accordance with the operating instructions, under the supervision of the licensed user(s).

REF: NRC 313 M - ITEM 16

Emergency Procedures

In the event of suspected damage, theft, or loss of a sealed source, the R.S.O. will be immediately notified. The contact points (manufacturer, supplier, nuclear consultant) for the R.S.O. have been previously identified in the "Shipment Receiving and Opening Procedures" herein, as are the appropriate actions in event of damage. In the event theft or loss is confirmed, the NRC would be notified as required by Title 10 Code of Federal Regulations (10 CFR), Part 20.402 and 20.403 regarding notifications of incidents.

REF: NRC 313 M - ITEM 17

Area Survey Procedures

As indicated in Item 9 "Instrumentation" and Item 10 "Calibration of Instruments" in this application, only a limited number of sealed sources, of relatively low activity and low energy, are involved with this application (no liquids, etc.). Supplier survey data and leak test certification are maintained on file. The time involved for source exchange handling is minimal, at generally less than five (5) minutes about every five (5) months. The sealed source in use is maintained in the shielded bone scanner device, which has a "day-of-use" display of the activity remaining in the sealed source. With all these considerations, the area survey procedures are considered either not applicable or these controls and methods represent the equivalent of area surveys.

REF: NRC 313 M - ITEM 18

Waste Disposal

All used sources will be returned to the supplier for disposal or transferred to any appropriately licensed recipient, in accordance with all applicable regulatory agency license, regulation and documentation requirements.

Leak Testing

A leak test certificate must be provided by the supplier with each sealed source shipment we receive. If the certification is not provided, we will notify the supplier to provide this data.

In the event we keep any sealed source for a period which will exceed six (6) months from the date on the initial leak test certificate provided with the source, we will have a leak test performed on the source before we return the source to the supplier. In the event we need to periodically perform these required semi-annual leak tests of sealed sources, we would use the Stan A. Huber Consultants, Inc. Model LT-2 Leak Test Kit, which is product certified with the NRC under license #12-17503-01.

Procedures and Precautions for Use of Radioactive Materials Specified in NRC 313M, Item 6b

- a) Each person involved with the handling of source shipments, source installation or exchange, or bone scanner usage will be trained in the basic radiation safety principles of time, distance, and shielding, as well as the applicable regulations and conditions of this license. These instructions will be delivered by the supplier or persons specifically authorized to provide such training, or by the Radiation Safety Officer of this license.
- b) Any person involved with source installation or exchange on the bone scanner will have had specific training in this task by the supplier or other persons specifically authorized to give such training, demonstration, and supervision. Alternately, the device supplier or their trained and authorized representatives may provide this source exchange service.
- c) The radioactive source is to be maintained in its shielded source holder at all times. Prior practice with inserting and removing a dummy (non-radioactive) source holder is necessary to reduce handling time to a minimum when handling an actual source. The source holder installation and exchange can easily be done in less than five (5) minutes. With a useful source life of about five (5) months, it is expected there will typically be about two (2) source exchanges for a bone scanner in any year.
- d) All persons involved with the licensed radioactive material at this facility are to be instructed and supervised by the R.S.O. in the previously described safety and emergency procedures contained in this license application, as well as the supplier instructions for source exchanges and users manual for the bone scanner, as applicable to each person's duties.