

APPLICATION FOR MATERIAL LICENSE

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

FEDERAL AGENCIES FILE APPLICATIONS WITH:

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

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

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

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30333

IF YOU ARE LOCATED IN:

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

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

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

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

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

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

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

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

- ☐ A. NEW LICENSE
☒ B. AMENDMENT TO LICENSE NUMBER 53-13519-01
☐ C. RENEWAL OF LICENSE NUMBER _____

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

Maui Memorial Hospital
Radioisotope Service
221 Mahalani St.
Wailuku, Maui, Hi. 96793

3. ADDRESSES WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED:
(Same as 2.)

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

James Bendon, M.D., RSO

TELEPHONE NUMBER

(803) 242-2052

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

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

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

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

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

9. FACILITY: 8512020596 851001
REGS LIC30
53-13519-01 PDR

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

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

FEE CATEGORY 7C AMOUNT ENCLOSURE \$ EXEMPT

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

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

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

SIGNATURE—CERTIFYING OFFICER

TYPED/PRINTED NAME

TITLE

DATE

Jerry Walker

Administrator

7/15/85

14. VOLUNTARY ECONOMIC DATA

A. ANNUAL RECEIPTS

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

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

C. NUMBER OF BEOS

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

☐ YES

☐ NO

FOR NRC USE ONLY

TYPE OF FEE

FEE LOG

FEE CATEGORY

COMMENTS

APPROVED BY

AMOUNT RECEIVED

CHECK NUMBER

DATE

FEE EXEMPT
170.11(a)(9)

70188 70228

LICENSED MATERIAL

ITEM 5 - Radioactive Material

Element and mass number: I-125

Chemical and/or physical form: Sealed source (AECL C-253 source in AECL C-236 source holder)

Maximum amount which will be possessed: 3 sources at 500 mCi per source

ITEM 6 - Purposes for Which Licensed Material Will Be Used

Use in OsteoAnalyzer Model No. SPSHA110, a bone mineral analyzer, for general medical use. The OsteoAnalyzer Model No. SPSHA110 has Certificate No. NR-525-D-101-S from the NRC Registry of Radioactive Sealed Sources and Devices.

ITEM 7 - Individual Responsible for Radiation Safety Program and Their Training and Experience.

James Bendon, M.D., RSO: Dr. Bendon has been authorized for use of materials listed in Item 6 of license number 53-13519-01 for uses in groups I, II, III, in vitro studies, & Xe133. Training and experience information is contained in the amendment application dated 4/30/80.

TRAINING AND EXPERIENCE

The following individuals will be Authorized Users. These are as per License No. 53-13519-01.

Eugene Wasson, III, M.D.

Groups I, II, III, IV and V

In vitro studies

Xenon 133

Strontium 90 ophthalmic applicator

James Bendon, M.D.

Groups I, II, and III

In vitro studies

Xenon 133

Thomas Abram, M.D.

Groups I, II, III

Iodine 131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, or thyroid carcinoma

Phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases

In vitro studies

Xenon 133

David Joseph Heeney, M.D.

Groups I, II, and III

Iodine 131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, or thyroid carcinoma

In vitro studies

Xenon 133

George Boren, M.D.

As authorized by present amendment application.

INSTRUMENTATION

Survey Instrument

Type: A low-level survey meter capable of detecting 0.1 mR/hr to perform radiation surveys.

Model: Eicron Surveyor 200 or equivalent.

Diagnostic Instrument

Type: Bone mineral analyzer; also know as bone densitometer.

Model: OsteoAnalyzer Model SPSHA110 bone mineral analyzer for performing diagnostic studies.

RADIATION SAFETY PROGRAM

ITEM 10 - Radiation Safety Program

1. SURVEY PROGRAM

1.1. The use of the sealed source in the bone mineral analyzer consists of placing the source in a fixed geometry position in the analyzer. Once it is in place, the shielding and beam direction cannot change unless the analyzer suffers some damage.

1.2. A radiation survey shall be performed on the bone mineral analyzer for each new source that is placed in the machine. The results of the survey shall be documented.

1.3. A radiation survey shall be performed in the storage area each time an additional source is placed in the storage area for long term storage. The results of these surveys shall be documented.

2. RECORDS MANAGEMENT PROGRAM

2.1. Records of radiation surveys of the bone mineral analyzer and the storage area shall be kept for five years.

2.2. Records of source receipt and transfer shall be kept for at least five years.

2.3. Records of leak tests of sealed sources shall be kept for at least five years.

2.4. Records of personnel exposure shall be kept indefinitely.

2.5. Records of source disposals shall be kept indefinitely.

2.6. Records shall be reviewed for completeness and accuracy semi-annually by the Radiation Safety Officer or his designate.

3. LEAK TEST PROCEDURES

3.1. Leak tests shall be performed on sources in use every six months. The leak tests shall be able to detect 0.005 uCi of activity. Results of the leak tests shall be documented. Leak tests shall be performed according to the following procedures:

3.1.1. Take a canvas wipe and wipe it around the joint between the source holder and source cap. Place the wipe in the folded paper envelope used to hold it.

3.1.2. Calibrate the laboratory counter with a mock iodine source. Count the mock iodine source for one minute.

3.1.3. Count background for one minute. Calculate the conversion factor for the detector as follows:

$$K = uCi / (C_s - C_b)$$

uCi = source activity
 C_s = source cnts per min
 C_b = bkgd cnts per min

3.1.4. Remove the source and take a one minute background count. Calculate the minimum detectable activity (MDA) and minimum detectable count rate (MDCR) according to the following formulas:

$$MDCR = 1.64 \times 2 \times C_b$$

$$MDA = K \times 1.64 \times 2 \times C_b$$

3.1.5. Count the wipe for 1 minute. If the measured count rate is less than MDCR, record the activity as <MDA. If the measured count rate is greater than MDCR, calculate and record the actual activity.

3.1.6. With typical counting equipment, this counting procedure will result in a MDA of less than 0.0005 uCi.

4. INSTRUCTION TO PERSONNEL

4.1. Personnel who use the I-125 sealed sources in the OsteoAnalyzer will either be specifically authorized by the license, or will have completed the in-house training program for users of the OsteoAnalyzer.

5. PACKAGE RECEIVING AND OPENING PROCEDURES

5.1. The I-125 sources are also less than Type A quantities of radioactive material. Consequently, no radiation surveys are required on receipt of the package. When shipped from the manufacturer, the packages carry a WHITE-I radioactive label, indicating that radiation levels on the surface are less than 0.5 mR/hr.

5.2. Open the outer shipping container. Open the inner shipping container with the brass source capsule. Take a canvas wipe and

wipe the brass source capsule. Analyze the wipe to verify² there is no removable contamination greater than 200 dpm/100 cm².

5.3. Verify the serial number on the source against the serial number on the shipping documents. Log the receipt of the source into the source receipt log.

5.4. Leave the source in the original shipping container until it is actually installed in the analyzer.

6. SOURCE REPLACEMENT PROCEDURES

6.1. Remove the outer cover of the scanner unit. Using the key for the source compartment, unlock and remove the cover from the source compartment.

6.2. Unscrew the source from the receptacle in the source compartment. Immediately screw on the brass cap on the source. Make sure the end of the source capsule with the threads is always pointed away from you when the cap is not on.

6.3. Place the source in the shipping container to be returned to the manufacturer.

6.4. Remove the new brass source capsule with the brass cap attached from the shipping container. Unscrew the cap from the source and screw the source into the receptacle in the source compartment. Make sure the end of the source capsule with the threads is always pointed away from you when the cap is not on.

6.5. Using the key, lock the source compartment cover in place. Remove the key and store it in a secure location.

6.6. Replace the cover on the scanner unit.

7. SOURCE PACKAGING AND SHIPPING PROCEDURES

7.1. Place the source with the cap tightly screwed on in the foam insert from the original shipping container.

7.2. Place the foam insert in the original inner container (metal can) and tape the lid on the can with fabric-backed tape.

7.3. Place the metal can in the original outer shipping box and tape the box closed with security tape.

7.4. Remove old shipping labels, packing slips, and other old labels from the box. Make sure the words "RADIOACTIVE MATERIAL", "TYPE 'A' PACKAGE", "I.A.E.A. C.T.C-12B25", and the manufacturer's name and address are still clearly legible on the box.

7.5. Place two new RADIOACTIVE WHITE-I labels over the old ones on the box. Enter I-125 as the contents. Calculate and enter the activity of the source.

7.6. Place a shipping label on the box with the name and address of the facility shipped from and shipped to.

7.7. Write or stamp the words "RADIOACTIVE MATERIAL, N.O.S." and "UN2982" on the box in letters at least 1/2" high.

7.8. Fill out the shipping papers for the shipment. The proper shipping name for the source is "Radioactive Material, N.O.S. (Iodine-125)" and the proper classification is "UN2982".

8. INVENTORY REQUIREMENTS

8.1. An inventory of all sources in use and in storage shall be made every six months. Records of the semi-annual inventories shall be kept.

9. EMERGENCY PROCEDURES

9.1. The low energy gamma and x-rays emitted from the I-125 source are completely absorbed by the brass source holder.

9.2. If for any reason the source is dropped when the cap is off, pick up the source by the end opposite the threaded end, being careful not to point the hole from the source window towards you. Pick up the brass source holder cap in your other hand and screw it on the source holder. This will totally shield any radiation coming from the source.

10. DUTIES AND RESPONSIBILITIES

10.1. The authorized users will be responsible for:

10.1.1. Receipt of sources and logging in the source receipt log.

10.1.2. Storage of sources received in the radioactive materials storage area.

10.1.3. Source replacement in the OsteoAnalyzer.

10.1.4. Packaging of sources for shipping and delivering to a carrier for shipment to the manufacturer.

10.1.5. Leak testing of sources in use over six months.

10.2. The Radiation Safety Officer will be responsible for the following:

10.2.1. Assuring that byproduct materials possessed under the license conform to the materials listed on the license.

10.2.2. Assuring that use of the device is only by individuals authorized by the license.

10.2.3. Assuring that all users wear personnel monitoring equipment when required.

10.2.4. Assuring that the sources are properly secured against unauthorized removal at all times when not in use.

10.2.5. Serving as a point of contact to give assistance in case of an emergency, and assuring that proper authorities are notified in case of an emergency.

10.2.6. Assuring that the terms and conditions of the license are met and that required records are periodically reviewed for compliance with NRC regulations and license conditions.

WASTE MANAGEMENT

1. Sources that have decayed below an acceptable level will be removed from the bone mineral analyzer and stored in a locked storage area.
2. The storage area will be posted with a "CAUTION - RADIOACTIVE MATERIALS" sign.
3. When sources are transferred to the source manufacturer for final disposal, the disposal shall be noted on the receipt/disposal log.
4. Sources will be returned to the manufacturer in the original shipping containers they were shipped in. The requirements of 10 CFR 49 shall be followed with regards to packing, labelling, marking, and surveying of the package and filling out the shipping documents.

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

George S. Boren, M.D.

STREET ADDRESS

St. Mark's Hospital

1200 East 3900 South

CITY

Salt Lake City,

STATE

Utah

ZIP CODE

84117

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.
3. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
I-131 or I-125 <i>or</i> I-123	DIAGNOSIS OF THYROID FUNCTION	24	Team hepatobiliary 8
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES	57	
	IN VITRO STUDIES	50	
OTHER			
I-125	DETECTION OF THROMBOSIS		Team MAA Venogram + Thrombo scintigram 6
I-131	THYROID IMAGING	24	
U-233 P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY ~ In-111	2	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	50	
OTHER			
Tc-99m	BRAIN IMAGING	45	Thallium 201 cardiac 50
	CARDIAC IMAGING	37	
	THYROID IMAGING	3	
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING	34	
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	145	
	LUNG IMAGING	50	
	BONE IMAGING	160	
OTHER			

PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELE THERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	50	
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	50	
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

4/14/80 Through 7/13/80 (3 months)
480 hours

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR

Dr Paul Brown

b. NAME OF INSTITUTION

Univ of Oregon Health Sciences Univ
and Portland Veterans Admin Hosp

c. MAILING ADDRESS

3181 SW Sam Jackson Park Road

d. CITY

Portland, Oregon 97201

5. MATERIALS LICENSE NUMBER(S)

ORE-0013-1

6. PRECEPTOR'S SIGNATURE

James Ernest Haines MD

7. PRECEPTOR'S NAME (Please type or print)

James Ernest Haines MD

8. DATE

11-30-83

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

St. Mark's Hospital

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

3. CERTIFICATION

SPECIALTY BOARD
A

CATEGORY
B

MONTH AND YEAR CERTIFIED
C

American Board of Radiology

Diagnostic Radiology

June 1980

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

University of Oregon Health
Sciences University
Portland, Oregon 1976-1980

40

40

b. RADIATION PROTECTION

12

c. MATHEMATICS PERTAINING TO
THE USE AND MEASUREMENT
OF RADIOACTIVITY

10

d. RADIATION BIOLOGY

26

e. RADIOPHARMACEUTICAL
CHEMISTRY

10

22

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

ISOTOPE

MAXIMUM AMOUNT

WHERE EXPERIENCE WAS GAINED

DURATION OF EXPERIENCE

TYPE OF USE

SEE CLINICAL EXPERIENCE

INSTRUMENTATION

1. Survey Meters

- A. Manufacturer's name: Picker Nuclear
Manufacturer's model number: 655-186
Number of instruments available: 1
Minimum range: 0 to 0.2 mR/hr
Maximum range: 0 to 2000 mR/hr
- B. Manufacturer's name: Victoreen Instrument Division
Manufacturer's model number: 6A
Number of instruments available: 1
Minimum range: 0 to 300 cpm and 0 - 0.5 mR/hr
Maximum range: 0 to 30,000 cpm and 0 - 50 mR/hr

2. Dose Calibrators

- A. Manufacturer's name: Radx
Manufacturer's model number: Mark V
- B. Manufacturer's name: Capintec
Manufacturer's model number: CRC 7

3. Diagnostic Instruments

<u>Type of Instrument</u>	<u>Manufacturer's Name</u>	<u>Model No.</u>
Scintillation Camera	Siemens	ZLC 750S & Scintiview
Scintillation Camera	Siemens	Pho/Gamma IV
Gamma Well Counter	Searle	8725
Thyroid Uptake Probe	Searle	----
Automatic Well Counter	Abbott	----
Automatic Gamma Counter	Abbott	ANZR

Item 9-1
Date: 4/29/85

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