NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 5-31-87

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
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

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

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

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
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
- [X] B. AMENDMENT TO LICENSE NUMBER 53-17797-01
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

Kuakini Hospital & Medical Center
347 N. Kuakini Street
Honolulu, HI 96817

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

Kuakini Hospital & Medical Center
347 N. Kuakini Street
Honolulu, HI 96817

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
Richard Wasnich, M.D. area code 808/547-9549, 547-9578

TELEPHONE NUMBER
531-6258

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

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

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

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

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

9. FACILITIES AND EQUIPMENT

8510230103 850820
REG5 LIC30
53-17797-01 PDR

10. RADIATION SAFETY PROGRAM.

11. WASTE

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY
AMOUNT ENCLOSED $

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
Gary K. Kajiwara	Gary K. Kajiwara	Sr. Vice President	07/29/85

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] <$250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

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

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)*
- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMD	Aug-1-tt 7C			
AMOUNT RECEIVED	CHECK NUMBER			DATE
1120	098999			8/12/85

PRIVACY ACT STATEMENT ON THE REVERSE

LICENSED MATERIAL

Item 5 - Radioactive Material

Element and mass number: I-125

Chemical and/or physical form: sealed source (AECL C-235 source in AECL C-236 source holder)

Maximum amount which will be possessed: 20 sources at 800 mCi per source

Item 6 - Purposes For Which Licensed Material Will Be Used

Use in Model SPSHAXXX bone mineral analyzer for performance testing and development, training, and demonstration. The Model SPSHAXXX bone mineral analyzer has received custom device approval from the NRC.

70235

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 in 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:

$$MDCR = 1.64 \times \sqrt{2 \times C_b}$$

$$MDA = K \times 1.64 \times \sqrt{2 \times C_b}$$

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 verify there is no removable contamination greater than 200 dpm/100 cm^2.

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.

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