

NRC FORM 313  
(10-2005)  
10 CFR 30, 32, 33,  
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/31/2008

Estimated burden per response to comply with this mandatory collection request: 4.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NE0B-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY  
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS  
U.S. NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM  
DIVISION OF NUCLEAR MATERIALS SAFETY  
U.S. NUCLEAR REGULATORY COMMISSION, REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH  
U.S. NUCLEAR REGULATORY COMMISSION, REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH  
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV  
611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TX 76011-4005

Dr. 1

SEP 14 AM 10:18

RECEIVED REGION I

03036506

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 JURISDICTIONS.

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

- A. NEW LICENSE
- B. AMENDMENT TO LICENSE NUMBER 52-30883-01
- C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Wifredo Rabelo Millán, MHSA  
P.O. Box 10011  
Guayama, P.R. 00785

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Hospital Episcopal Cristo Redentor, Inc.  
Nuclear Medicine Dept.  
P.O. Box 10011  
Guayama, P.R. 00785

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Carmelo Pérez, Physicist, RSO  
TELEPHONE NUMBER OC. (787) 432-9320  
@ (787) 864-4300-Ext. 2356 o 2270

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 EXPERIENCE.

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE 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, 36, 39, 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.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Wifredo Rabelo Millán, MHSA

SIGNATURE

DATE

8/27/2006

FOR NRC USE ONLY

| TYPE OF FEE | FEE LOG | FEE CATEGORY | AMOUNT RECEIVED | CHECK NUMBER | COMMENTS |
|-------------|---------|--------------|-----------------|--------------|----------|
|             |         |              | \$              |              |          |

APPROVED BY

DATE



Hospital Episcopal  
**Cristo Redentor**

August 27, 2006

Pamela J. Henderson  
Licensing Assistance Team  
Division of Nuclear Medicine Materials Safety  
U.S. Nuclear Regulatory Commission, Region I  
King of Prussia, PA 19406-1415

SUBJ: Amendments to License No. 52-30883-01  
Docket number: 030-36506

It is hereby requested that the following amendments be added to our license:

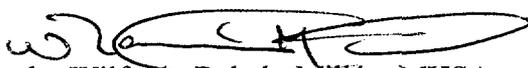
1. The Department of Nuclear Medicine was Modified, please add the map (Attachment A) that describe the changes in the area.
2. Include in the license Jose Barreras Rincón, MD as authorized user for medical use 35.100, 35.200, 35.300. See previous license. He was an authorized user under license no. 52-21325-01.
3. Add in the item 7 Chemical and/ or Physical from for part 35.400 the Brachytherapy Sealed Source Model Listed Below

Add: IsoAid LLC Model IAA 125A

Attached is a copy of the Registry of Sealed Sources and Devices Safety Evaluation (FL-1146-S101-S) for this model Brachytherapy Seed.

Thank you for your cooperation.  
Please contact me if you have any questions about the amendment request

Sincerely,

  
Lcdo. Wilfredo Rabelo Millán, MHSA  
Hospital Episcopal Cristo Redentor, Administrator

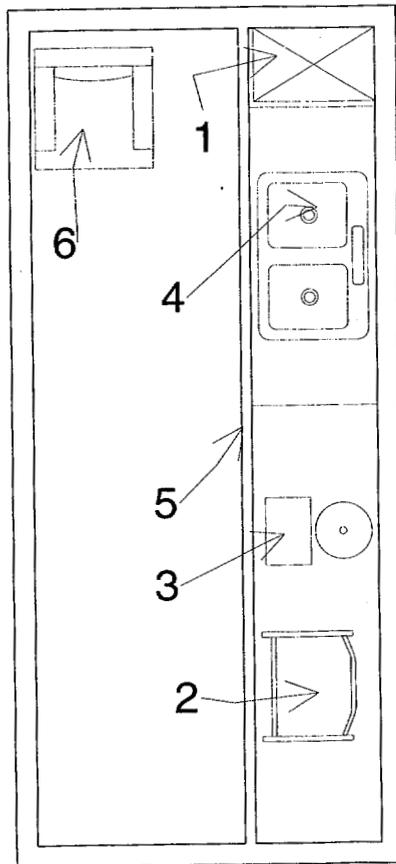
Attachments:

1. Form 313
2. Attachment A Diagram Map
3. Registry of Sealed Sources

# ATTACHMENT A

## HOSPITAL EPISCOPAL CRISTO REDENTOR INC

### NUCLEAR MEDICINE DEPARTMENT HOT ROOM



#### DESCRIPTION

1. Fume Hood
2. L-Block Lead Shield
3. Dose Calibrator
4. Sink
5. Cabinet with Lead Shield  
Storage for waste Disposal (I - 131)
6. Injection Site

LIVING AREA

83 sq ft

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION

NO: FL-1146-S-101-S

DATE: June 25, 2002  
Revision 1 Amended Pages 1 and 4

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SEALED SOURCE TYPE:

Brachytherapy Seed

DESCRIPTION:

The IsoAid L.L.C. Model IAI-125A source is an interstitial brachytherapy seed. The Model IAI-125A seed contains iodine 125 adsorbed onto a 0.5 millimeter diameter, 3 millimeter long silver rod. The rod is encased in a 0.8 millimeter diameter, 4.5 millimeter length titanium tube with a wall thickness of 0.05 millimeter. The tube is laser welded shut at both ends, hermetically sealing the radioactive silver rod inside. See the diagram in attachment 1.

The Model IAI-125A seeds are checked for welding integrity microscopically ultrasonically cleaned and leak tested in accordance with International Standard ISO-9978. Seeds that pass the leak test are assayed for determination of Air Kerma and Apparent Activity. The seeds are sorted by activity and stored for distribution.

LABELING:

The small size of the individual seeds prevents labeling of each seed. Seeds are sorted and grouped by apparent activity range, assigned a unique lot number and placed in a 4 milliliter glass vial and a polyethylene lined lead brick for storage and eventual distribution. Affixed to the individual vials is a label stating "Caution: Radioactive Materials", isotope, Apparent activity or Total Apparent Activity, reference date, manufacturer's logo and the trefoil radiation symbol. An additional label is affixed to the lead shielded storage container in which a vial is placed stating "Caution: Radioactive Material", product description, Apparent or Total Apparent activity, number of sources, reference date, manufacturer's logo and a warning against distribution to unauthorized persons. The label complies with the provisions of 64E-5, Florida Administrative Code Subsection 64E-5.210(12).

DIAGRAM:

See attachment 1

CONDITIONS OF NORMAL USE:

The Model IAI-125A source is designed for use in the interstitial treatment of cancerous tissue. These sources are not sterile when shipped which is stated on the label affixed to the vial. Testing of the source indicated they can withstand a maximum temperature of 600°C (1112°F) and pressure of 290 psi.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
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SEALED SOURCE TYPE:

Brachytherapy Seed

PROTOTYPE TESTING:

These sources were tested in accordance with ISO-2919 and leak tested following each test in accordance with ISO-9978. The ISO-2919 procedure involves testing of source for impact, temperature and pressure. Six sources were selected for testing, with two sources used to conduct each test. No source after testing indicated leakage activity above 5 nanocuries. The results of the prototype testing indicate the IsoAid Model IAI-125A (Advantage™ I-125) brachytherapy seed has a classification designation of ISO/01/C53211.

EXTERNAL RADIATION LEVELS:

External radiation levels from the Model IAI-125A brachytherapy seed were determined by using an ionization chamber and the inverse square law with the following results:

Exposure Rate from a 0.191 mCi (7.03MBq) Seed

| Distance From Source (cm) | Exposure Rate (mR/hr) - (μGy/hr) |
|---------------------------|----------------------------------|
| 5                         | 15.4      154                    |
| 15                        | 3.3        33                    |
| 30                        | 0.7        7                     |
| 50                        | 0.4        4                     |
| 100                       | 0.2        2                     |

Estimated dose from a 5 mCi (185MBq) seed

| Distance from source (cm) | Estimated Dose Rate (mrem/hr) - (mSv/hr) |
|---------------------------|--|
| 5                         | 2591.8      25.92                        |
| 15                        | 288.0       2.88                         |
| 30                        | 72.0        0.72                         |
| 50                        | 25.9        0.26                         |
| 100                       | 6.5         0.065                        |

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
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SEALED SOURCE TYPE: Brachytherapy Seed

QUALITY ASSURANCE AND CONTROL:

IsoAid, L.L.C. conducts the following quality control tests and inspection of the Model IAI-125A brachytherapy seed prior to distribution: visual inspection of the weld, ultrasonic cleaning, initial leak test and assay for activity. The IsoAid, L.L.C. quality control procedures are compatible with ISO 9001 standard and U.S. Nuclear Regulatory Commission Regulatory Guide 6.9.

LIMITATIONS OR OTHER CONSIDERATIONS OF USE:

- ⇒ These sources shall be distributed to persons who are specifically licensed.
- ⇒ The sources shall not be exposed to temperatures in excess of 138°C (280°F) and pressures in excess of 290 psi.
- ⇒ Sources shall be leak tested at intervals not to exceed 6 months. The test shall be capable of detecting the presence of 0.005 microcurie of iodine 125.
- ⇒ Handling, storage, use, transfer and disposal of these specifically licensed sources are to be determined by the licensing authority.
- ⇒ Sources are supplied non-sterile. Sterilization must be performed prior to implantation.
- ⇒ This registration sheet and the information contained within the references shall not be changed without the written consent of the State of Florida, Bureau of Radiation Control.

SAFETY ANALYSIS SUMMARY:

Based on the review of the information and test data cited below, and the past history of the design of similar sources, we conclude that the Model IAI-125A brachytherapy seed is acceptable for specific licensing purposes. Furthermore, we continue to conclude that these sources are expected to maintain their containment integrity for normal and accidental conditions of use, which might occur during the uses specified in this registration certificate.

REFERENCES:

The following supporting documents for the Model IAI-125A brachytherapy seed are hereby incorporated by reference and are made a part of this registration document:

Correspondence dated: May 29, 2001 with attachments;  
July 18, 2001 with attachments; and  
June 5, 2002.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION

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SEALED SOURCE TYPE:

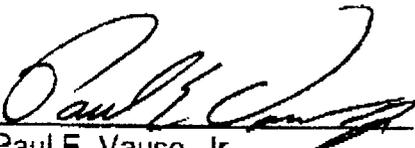
Brachytherapy Seed

The information provided by the manufacturer for distribution of the Model IAI-125A brachytherapy seed is incorporated into the IsoAid L.L.C., State of Florida, Radioactive Materials License Number 3196-1.

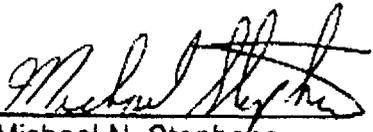
ISSUING AGENCY:

State of Florida  
Department of Health  
Bureau of Radiation Control  
Radioactive Materials Program  
Bin # C21  
4052 Bald Cypress Way  
Tallahassee, FL 32399-1741  
(850) 245-4545

Reviewed By:

  
Paul E. Vause, Jr.  
Environmental Manager

Concurrence:

  
Michael N. Stephens  
Environmental Administrator

Date: June 25, 2002

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION

NO: FL-1146-S-101-S

DATE: June 25, 2002

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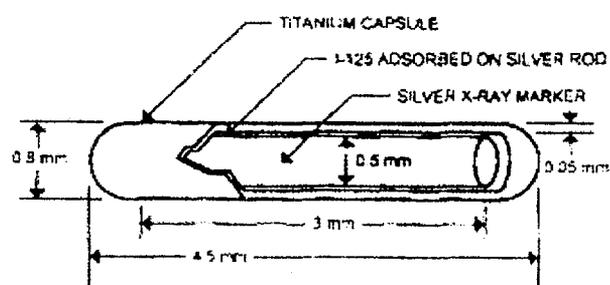
Revision 1

Revision 1 Amended Pages 1 and 4

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DEVICE TYPE:

Brachytherapy Seed



ADVANTAGE™ I-125

Figure 1. Nominal Iodine-125 Seed.

This is to acknowledge the receipt of your letter/application dated

8/27/2006, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 52-30883-01  
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 139403.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (R1)  
(8-88)

Sincerely,  
Licensing Assistance Team Leader