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Br. 1

HIMA San Pablo Caguas
Caguas, PR 00726

August 13, 2009

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

Subject: Amendment to Radioactive Materials License No. # 52-25019, -01
Docket No. 030-30826

We request to amend our radioactive materials license to include an additional Brachytherapy source from ISOAID. The source and model number is I-125, Model #IAI-125A. The manufacture and source information is attached.

If you have questions or concerns regarding our amendment request, please contact our Radiation Safety Officer, Carmelo Pérez, at (787)432-9320.

Sincerely,

Carlos M. Piñeiro
President

Attachments:
Attachment A
NRC Form 313
ISOAID Source Description

RLT

RECEIVED
REGION 1
2009 AUG 20 AM 10:46

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NRC/RGNI MATER. ALS-002

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HOSPITAL HIMA SAN PABLO CAGUAS

ATTACHMENT A

I. NEW SOURCE

1. For I-125

- a. Manufacturer – ISOAID ADVANTAGE**
- b. Model – I-125 (IAI-125A)**

II. RADIOACTIVE MATERIAL AND PURPOSE

Byproduct Material	Chemical/Physical form	Maximum Amount	Purpose
35.400 (f)- I-125	Sealed source	2 Curies	Medical Use
35.400 (g)- I-125	Sealed source	2 Curies	Medical Use

NRC FORM 313

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

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

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, NEOB-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.

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

03030826

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

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 52-25019-01
- C. RENEWAL OF LICENSE NUMBER _____

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

Carlos Piñero, MHA
Hospital HIMA San Pablo Caguas
P.O. Box 4980
Caguas P.R. 00726-4980

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Carmelo Pérez, Medical Physicist, RSO

TELEPHONE NUMBER

(787) 432-9320

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.

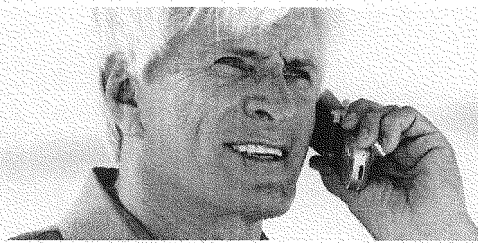
CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE
CARLOS M. PIÑERO, PRESIDENT

SIGNATURE 

DATE 8/12/09

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	



ISOAID ADVANTAGE™ I-125 (IAI-125A)

Dosimetry Parameters

The dosimetric characteristics of IsoAid ADVANTAGE™ (model IAI-125A) I-125 source have been determined according to the Updated AAPM Task Group 43 (TG43U1) recommendations¹. The values presented here are based on AAPM-approved consensus datasets².

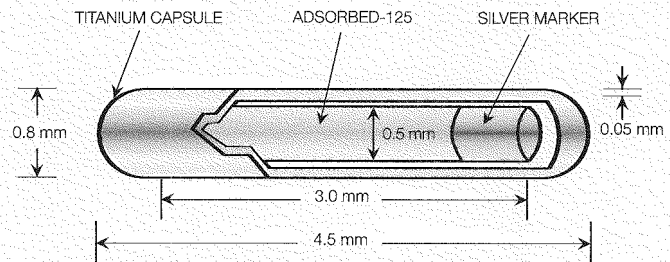
Consensus dose rate constant value²

$$\text{Dose Rate Constant } \Lambda_{\text{con}} = 0.981 \text{ cGy/h/U}$$

AAPM Consensus line source approximation radial dose function ($g_r(r)$) and point source approximation radial dose function ($g_p(r)$)²

Distance (cm)	Radial Dose Function $g_L(r)$	Radial Dose Function $g_P(r)$
0.0	1.040	0.686
0.10	1.040	0.686
0.15	1.053	0.833
0.25	1.066	0.967
0.50	1.080	1.056
0.75	1.035	1.029
1.00	1.000	1.000
1.50	0.902	0.906
2.00	0.800	0.804
3.00	0.611	0.615
4.00	0.468	0.471
5.00	0.368	0.371
6.00	0.294	0.296
7.00	0.227	0.229
8.00	0.165	0.166
9.00	0.141	0.142
10.00	0.090	0.091

NOTE: $g(r)$ at 0.0cm equals $g(r_{\text{max}})$ as recommended by AAPM Task Group No. 43U1 Report



IsoAid ADVANTAGE™ (model IAI-125A) I-125 source

AAPM consensus 2D and 1D Anisotropy Functions²

Angle θ (Degree)	2D Anisotropy Function, $F(r, \theta)$					
	0.5cm	1.0cm	2.0cm	3.0cm	5.0cm	7.0cm
0	0.352	0.406	0.493	0.520	0.578	0.612
5	0.411	0.465	0.545	0.584	0.658	0.701
10	0.481	0.527	0.601	0.642	0.704	0.726
20	0.699	0.719	0.757	0.775	0.794	0.799
30	0.848	0.846	0.862	0.862	0.869	0.879
40	0.948	0.936	0.932	0.916	0.937	0.969
50	1.002	0.986	0.974	0.961	0.963	0.971
60	1.029	1.024	1.008	0.993	0.990	1.001
70	1.029	1.039	1.027	1.006	1.016	1.010
80	0.999	1.025	1.024	1.023	1.009	1.025
90	1.000	1.000	1.000	1.000	1.000	1.000
$\Phi_{\text{an}}(r)$	0.957	0.968	0.964	0.955	0.959	0.955

Polynomial Equation

$$g_L(r) = a_0 + a_1 r + a_2 r^2 + a_3 r^3 + a_4 r^4 + a_5 r^5$$

Where:

$$\begin{aligned} a_0 &= 1.0549\text{E}+0 & a_1 &= 5.8111\text{E}-2 \\ a_2 &= -1.5048\text{E}-1 & a_3 &= 3.7413\text{E}-2 \\ a_4 &= -3.7008\text{E}-3 & a_5 &= 1.3103\text{E}-4 \end{aligned}$$

References

1. M.J. Rivard, B.M. Coursey, L.A. DeWerd, W.F. Hanson, M.S. Huq, G.S. Ibbott, M.G. Mitch, R. Nath, J.F. Williamson, "Update of AAPM Task Group No. 43 Report: A revised AAPM protocol for brachy-therapy dose calculations," Med Phys. 31(3) (2004) 633-674.
2. M.J. Rivard, W.M. Buttler, L.A. DeWerd, M.S. Huq, G.S. Ibbott, A.S. Meigooni, C.S. Melhu s, M.G. Mitch, R. Nath, J.F. Williamson. "Supplement to the 2004 update of the AAPM Task Group No. 43 Report," Med. Phys. 34(6) 2187-2205.

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

8/13/09, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (52-25019-01) 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

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** 144077.
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 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader