



Radiology
200 Jefferson, SE
Grand Rapids, MI 49503
Phone: 616.752.6744, FAX: 616.732.3066
www.smhealthcare.org

Fax

To: Materials Licensing Branch
Nuclear Regulatory Agency
Region III

From: Dale Schippers, RSO

Fax: (630) 515-1078

Pages: 8

Phone:

Date: Wednesday, July 11, 2007

Re: License Amendment Request

CC:

Comments:



Saint Mary's Health Care
200 Jefferson, S.E.
Grand Rapids, MI 49503

July 11, 2007

Materials Licensing Branch
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

RE: Amendment of License: 21-01078-01
(Current Amendment No. 75)

To Whom It May Concern:

Saint Mary's Health Care is requesting that the referenced Materials License be amended as follows:

Item 7 Chemical or Physical Form

D. Sealed Sources

Add: IsoAid LLC Model IAI 125 A

Attached is a copy of the Registry of Sealed Sources and Devices Safety Evaluation (FL-1146-S-101-S) for this model Brachytherapy Seed.

Please expedite this amendment request as we have patients waiting for treatment and no source for I-125 seeds. Our previous supplier has discontinued their sales of I-125 seeds and has provided very little notice regarding this change.

Please contact me if you have any questions about this amendment request.

Sincerely,

A handwritten signature in black ink that reads 'Dale Schippers'.

Dale Schippers M.S.
Radiation Safety Officer

A handwritten signature in black ink that reads 'Earl Monks'.

Earl Monks
Director of Radiology

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

PAGE 1 of 6

SEALED SOURCE TYPE:

Brachytherapy Seed

MODEL:

IAI-125A (AdvantageTM I-125)

MANUFACTURER:
& DISTRIBUTOR:

IsoAid, L.L.C.
7824 Clark Moody Boulevard
Port FL 34668

ISOTOPE:

MAXIMUM ACTIVITY:

Iodine 125

10 millicuries (370 MBq)

LEAK TEST FREQUENCY:

6 months

PRINCIPAL USE:

(V) General Medical Use

CUSTOM DEVICE:

____ YES

X NO

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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.

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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

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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.

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SEALED SOURCE TYPE:

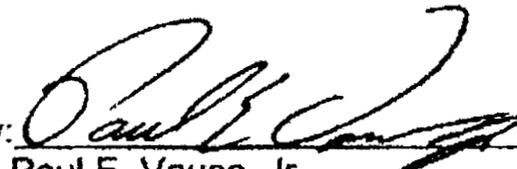
Brachytherapy Seed

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.

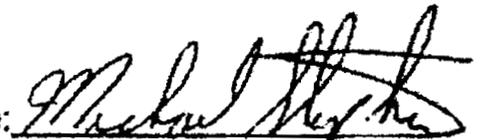
ISSUING AGENCY:

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

2007 07/11 16:36:30
Jul 11, 2007 11:46AM

No. 0105 P. 7

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION

NO: FL-1146-S-101-S

DATE: June 25, 2002

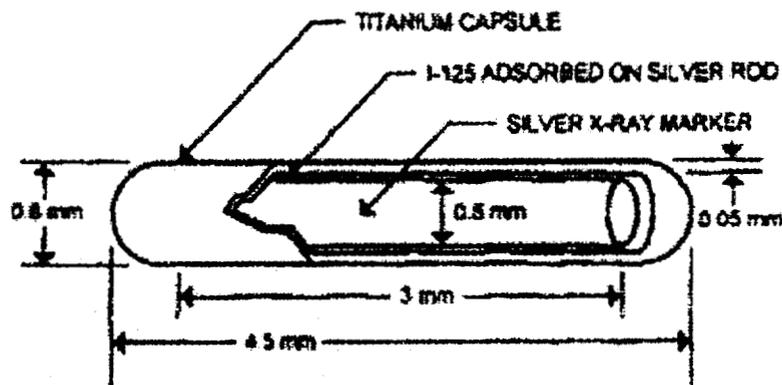
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Revision 1

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DEVICE TYPE:

Brachytherapy Seed



ADVANTAGE™ I-125

Figure 1. Nominal Iodine-125 Seed.