

## REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

**INSTRUCTIONS:** Send this request AND a copy of all related letters/applications and drawings to the Chief, Sealed Source Safety Section, OWFN  
Mail Stop O-8 111. Change the License Tracking System milestone to 19 and assign to reviewer code 1-5.  
**NOTE:** Retain a copy of this request with the application and background files.

<b>REQUESTER</b> <b>Mills Biopharmaceutical, Inc.</b> TELEPHONE NUMBER _____ DATE _____ NAME OF APPLICANT <b>Steven Jackson</b> MAIL CONTROL NUMBER(S) _____ LETTER/APPLICATION DATE <b>10/24/2003</b> LICENSE NUMBER(S) _____	<b>REGION/LOCATION:</b> <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV     <input type="checkbox"/> HQ     <input type="checkbox"/> LFARB <b>TYPE OF ACTION REQUESTED (Check as appropriate)</b> <input type="checkbox"/> SOURCE REVIEW <input checked="" type="checkbox"/> AMENDMENT OF <input type="checkbox"/> DEVICE REVIEW         REGISTRATION SHEET <input type="checkbox"/> CUSTOM REVIEW             NUMBER(S) <span style="float: right;"><b>NR-1081-S-101-S</b></span>
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**COMMENTS:**  
**120 N.E. 26th Street**  
**Oklahoma City, OK 73165**

FOR SSSS USE ONLY		
<b>REVIEWER</b> <b>Jonathan Rivera &amp; Ujagar Bhachu</b>	<b>MODEL NUMBERS</b> <b>Pd-103 SH &amp; Pd-103 SL</b>	<b>NUMBER ASSIGNED</b> <b>04-07</b>
<b>DATE RECEIVED</b> <b>10/27/2003</b>	<b>DATE ASSIGNED</b> <b>10/28/2003</b>	<b>DATE TO FEES</b> <b>10/28/2003</b>

TYPE OF ACTION (Indicate the number of each type)			
<input checked="" type="checkbox"/> <b>COMMERCIAL DISTRIBUTION (FORMAL)</b>		<input type="checkbox"/> <b>USE BY A SINGLE APPLICANT (CUSTOM)</b>	
<b>SOURCE (9C)</b>	<b>DEVICE (9A)</b>	<b>SOURCE (9D)</b>	<b>DEVICE (9B)</b>
<input type="checkbox"/> NEW <input checked="" type="checkbox"/> AMENDMENT	<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT	<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT	<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT
<input checked="" type="checkbox"/> <b>NO SAFETY EVALUATION REQUIRED NO FEES REQUIRED</b>		<input type="checkbox"/> <b>LICENSING ACTION REQUIRED (IF KNOWN)</b>	
		<input type="checkbox"/> YES <input type="checkbox"/> NO	

<input type="checkbox"/> <b>OTHER (Specify)</b>  TOTAL NUMBER OF REVIEW HOURS _____ NUMBER OF DEFICIENCY LETTERS _____ NUMBER OF DEFICIENCY CALLS _____	<b>NOTES</b> <b>Request to amend above-noted registration certificate in the construction of their Palladium 103 seed.</b>
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FOR FEE USE ONLY			
<b>TYPE OF FEE</b>	<b>FEE CATEGORY</b> <input type="checkbox"/> 9A <input type="checkbox"/> 9B <input type="checkbox"/> 9C <input type="checkbox"/> 9D		
<b>AMOUNT RECEIVED</b>	<b>CHECK NUMBER</b>	<b>DATE OF CHECK</b>	<b>LOG</b>
<b>APPROVED BY</b>	<b>DATE OF RETURN</b>		
<b>COMMENTS</b>			



# MENTOR

120 N.E 26th Street  
Oklahoma City, OK 73165 USA  
(405) 525-3141  
[www.mentorcorp.com](http://www.mentorcorp.com)



Subsidiary of Mentor Corporation

United States Nuclear Regulatory Commission  
Materials Safety Branch  
Division of Industrial and Medical Nuclear Safety  
Two White Flint North  
11545 Rockville Pike  
Mail Stop 8F5  
Rockville, Maryland 20814

**Re: NR-1081-S-101-S**

October 24, 2003

To Whom It May Concern:

This letter is to advise you that we are making a change in the construction of our Palladium-103 seed as described in the letter to the NRC dated July 29, 2001 which is listed in the References section of "Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Sealed Source" No. NR-1081-S-101-S.

The July 29, 2001 letter states that "Both I-125 and Pd-103 models contain five silver spheres. All silver spheres are coated with radioactivity, i.e. we do not manufacture the sources with inert spheres for spacing purposes." Prior to the market launch of the Pd-103 seed it was determined that therapeutic effectiveness of the seed could be improved by reducing the number of radioactive spheres in the seed to two, and placing them in the sealed Titanium shell in a 1 HOT, 3 COLD, 1 HOT configuration. This change does not adversely impact the safety or effectiveness of the seed as described in this referenced Registration Certificate.

We are also clarifying the same statement for the I-125 seed. While all silver spheres used in the I-125 seed will remain radioactive, the seed may contain three – five spheres as stated in the Registration Certificate No. NR-1081-S-101-S dated December 1, 1999.



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Enclosed is our amended Sealed Source Device Evaluation and Registration including Iodine-125 and Palladium-103. Based on our discussion with your office there are no associated fees in relationship with this amendment.

If there are any questions regarding this amendment, please contact me at either number below.

Respectfully,

Steven Jackson  
Director Quality Assurance/Regulatory Affairs  
Mentor, Corp.  
Mills Biopharmaceuticals, Inc.  
120 NE 26<sup>th</sup> St.  
Oklahoma City, OK 73105  
Work Phone: 405-523-1866  
Cell Phone: 405-820-4392  
Fax: 405-525-3143

(10-2002)  
10 CFR 30, 32, 33,  
34, 35, 36, 39, and 40

Estimated burden per response to comply with this mandatory collection request: 7 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 Management Branch (T-6 E6), 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.

# 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:**

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

LICENSING ASSISTANT SECTION  
NUCLEAR MATERIALS SAFETY BRANCH  
U.S. NUCLEAR REGULATORY COMMISSION, REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA PA 19406-1415

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

SAM NUNN ATLANTA FEDERAL CENTER  
U. S. NUCLEAR REGULATORY COMMISSION, REGION II  
61 FORSYTH STREET, S.W., SUITE 23T85  
ATLANTA, GEORGIA 30303-8931

**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  
801 WARRENVILLE RD.  
LISLE, IL 60532-4351

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 SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV  
611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TX 76011-8064

**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 NR-1081-S-101-S
- C. RENEWAL OF LICENSE NUMBER \_\_\_\_\_

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

Mills Biopharmaceuticals, Inc.  
120 NE 26th St.  
Oklahoma City, OK 73105

**3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED**

Mills Biopharmaceuticals, Inc.  
120 NE 26th St.  
Oklahoma City, OK 73105

**4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION**

Dr. Stanley Mills Ph. D. R. Ph.

**TELEPHONE NUMBER**

(405) 523-1864

**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

**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 \$ 0.00

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

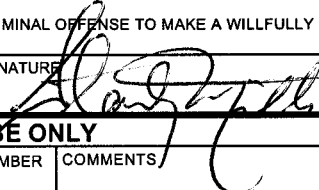
THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND 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

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE

Dr. Stanley Mills Ph. D. R. Ph.

SIGNATURE



DATE

24 Oct 03

**FOR NRC USE ONLY**

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

# AMMENDMENT and CORRECTION TO APPLICATION FOR REGISTRATION OF BRACHYTHERAPY SEED FOR MEDICAL USE

## DESCRIPTION

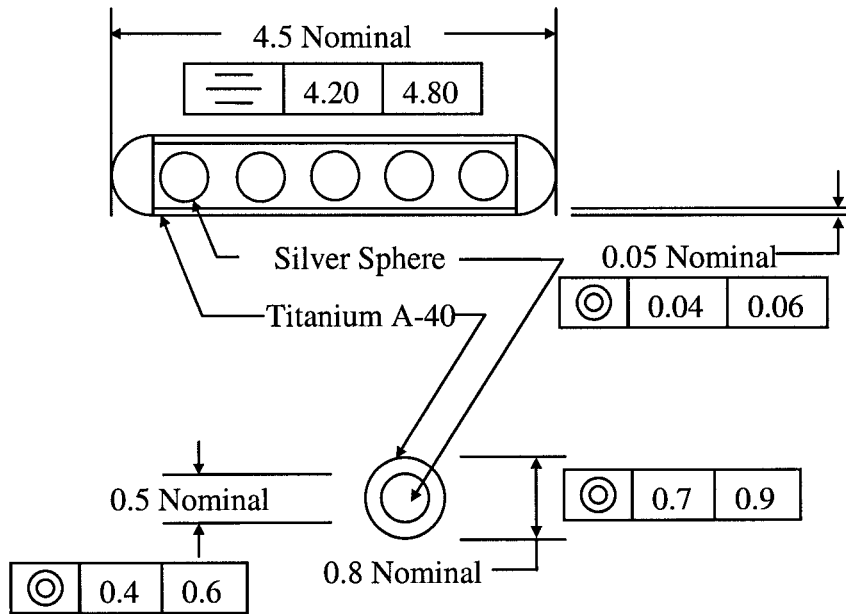
The Mills Biopharmaceuticals, Inc. (MBI) Model I-125 SL and I-125 SH seeds contain sodium iodine-125 absorbed on silver spheres and encapsulated in a cylindrical titanium capsule. As indicated in Attachment 1, the core of the silver seed is a  $0.5 \text{ mm} \pm 0.05 \text{ mm}$  ( $0.02'' \pm 0.002''$ ) sphere. Each MBI I-125 seed's maximum external dimensions are  $4.5 \text{ mm}$  ( $0.177''$ )  $\pm 0.3 \text{ mm}$  ( $0.0118''$ ) in length and  $0.80 \text{ mm}$  ( $0.01315''$ )  $\pm 0.1 \text{ mm}$  ( $0.004''$ ) in diameter. The cylindrical metal casing is A-40 (commercially pure) titanium, conforming to ASTM F-67-95, with a wall thickness of  $0.05 \text{ mm}$  ( $0.002''$ )  $\pm 0.01 \text{ mm}$  ( $0.0004''$ ). The titanium tubing is welded at one end, inverted, the spheres added, and the open end is closed with a weld. The welds are made in a vertical position in the presence of a gentle flow of high purity argon to consistently achieve good quality high strength welds.

Both models contain **three to five** silver spheres. The Model I-125 SH contains a maximum activity of 150 mCi (5.55 GBq) and the Model I-125 SL contains a maximum activity of 1 mCi (37 MBq). The two models differ only in total radioactivity contained.

The Model Pd-103 SH and Pd-103 SL seeds contain palladium-103 on the solid silver spheres. Physical dimensions of both the silver spheres and titanium casting if the Model Pd-103 SH and Pd-103 SL seeds are identical to those of the iodine seeds as described above. **The titanium tubing is welded on one end, inverted, five spheres are added in a 1 hot – 3 cold – 1 hot configuration, and the remaining end is welded closed (See attachment 2).** The Model Pd-103 SH contains a maximum activity of 185 MBq (5 mCi) and the Model Pd-103 SL contains a maximum activity of 111 MBq (3.00 mCi). The two models differ only in total radioactivity contained.

**Attachment 1**

**Construction of ProstaSeed I-125**



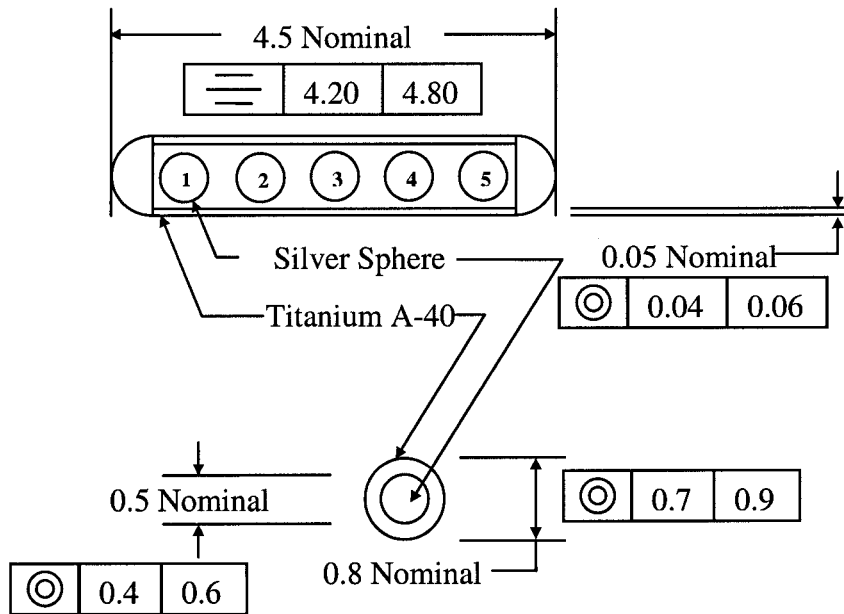
ProstaSeed I-125

1. All dimensions in millimeters
2. Not drawn to scale
3. The seed may contain 3 to 5 silver spheres
4. All five silver spheres are radiolabeled with Iodine - 125

**Attachment 2**

**Construction of ProstaSeed Pd-103**





ProstaSeed Pd-103

1. All dimensions in millimeters
2. Not drawn to scale
3. The seed will contain 5 silver spheres
4. Silver spheres 1 and 5 are radiolabeled with Pd-103
5. Silver spheres 2, 3 and 4 are non-radiolabeled (inert) used for spacing