Mills
Biopharmaceuticals, Inc.

120 N.E. 26TH STREET
OKLAHOMA CITY, OKLAHOMA 73105
405-525-3141
405-525-3143 FAX

August 2, 1999

Mr. Sudhamay Basu
U.S. N.R.C.
Materials Safety Branch
Division of Industrial and Medical Nuclear Safety
Two White Flint North Rockville Pike
North Bethesda, MD 50852

Dear Mr. Basu:

Pursuant to our telephone conversation enclosed are the raw material specification sheets for argon, silver spheres, sodium iodine-125, and titanium tubing. Following an extensive review of the literature brachytherapy sources containing iodine-125 have been used for almost 30 years and are considered safe and effective by the medical community.

MBI manufactures our brachytherapy sources by an automated proprietary process. In brief, the tubing is laser welded in the vertical position under a gentle flow of high purity argon to provide a consistent high strength weld. The process we developed replaces the more traditional process of hand welding the sources thus reducing the potential for human error and inconsistent welds.

As indicated in our original submission our source is similar to the current approved therapeutic seed source recently registered by International Isotope, Inc registry number TX-1068-S-101-S. MBI's seeds utilize silver to produce silver iodine, which is virtually water insoluble. Several silver spheres are encapsulated in medical grade titanium of similar dimensions by laser welding. Attached are two-product literature sheets provided by Imagyn and International Isotopes, Inc. describing their product and a NRC registry for Model IS 125.

Sincerely,

Stanley L. Mills, Ph.D., R.Ph.
President and CEO

Mills Biopharmaceuticals Inc.
Raw Material Specification Sheet

Material: Sodium Iodide I-125
Part Number: 0125
Grade: Radioactive

Acceptable Manufacturers: MDS Nordion

Appearance: Yellow-Orange Liquid

pH 8.0 – 11

Chemical Composition:

Iodates	≤2.%

Radionuclidic Purity

I-125	≥99.9%
I-126	≤0.005%
Cs-137 + Cs-134	≤0.001%

Approvals:

Quality Control: [signature] **Date:** 8/2/99

Quality Assurance: [signature] **Date:** 2 Aug 1999

Mills Biopharmaceuticals Inc.
Raw Material Specification Sheet

Material: Silver Spheres
Part Number: 0020
Grade: Equivalent to ASTM

Acceptable Manufacturers: Scientific Alloy Company

Size: Diameter 0.0195" to 0.0205"

Appearance: Spheres without burrs, Bright Silver Color

Chemical Composition:

Silver ≥ 99.99%

Not more than 0.01% total of the following impurities:

Gold	Silicon
Cadmium	Iron
Cobalt	Zinc
Copper	Nickel
Antimony	Aluminum
Arsenic	Palladium
Lead	Molybdenum
Mercury	

(Analysis by ASTM Method using ICP/MS or equivalent)

Approvals:

Quality Control: _____ **Date:** 8/2/99

Quality Assurance: _____ **Date:** 2 Aug 1999

Mills Biopharmaceuticals Inc.
Raw Material Specification Sheet

Material: Argon Gas
Part Number:
Grade: High Purity

Acceptable Manufacturers: Air Gas

Appearance: Clear, Colorless gas

Moisture: < 5 ppm

Chemical Composition:

Argon:	99.995%
Oxygen	< 5 ppm
Nitrogen	< 5 ppm

Approvals:

Quality Control: _____ **Date:** 8/2/99

Quality Assurance: _____ **Date:** 2 Aug 1999

Mills Biopharmaceuticals Inc.
Raw Material Specification Sheet

Material: Titanium Tubing
Part Number: 0010
Grade: Equivalent to ASTM F-67, Rev 95

Acceptable Manufacturers: Uniform Tubes

Size:

Outside Diameter (OD)	0.0305 to 0.0325
Length	0.2706 to 0.2766
Wall	0.0015 to 0.0025

Appearance: Tubes without burrs, Ends cut square

Chemical Composition:

Nitrogen	≤0.03%
Carbon	≤0.10%
Hydrogen	≤0.015%
Iron	≤0.30%
Oxygen	≤0.25%
Titanium	≥99.30%

(Analysis by ASTM Methods or by Auger Mass Spectroscopy)

Approvals:

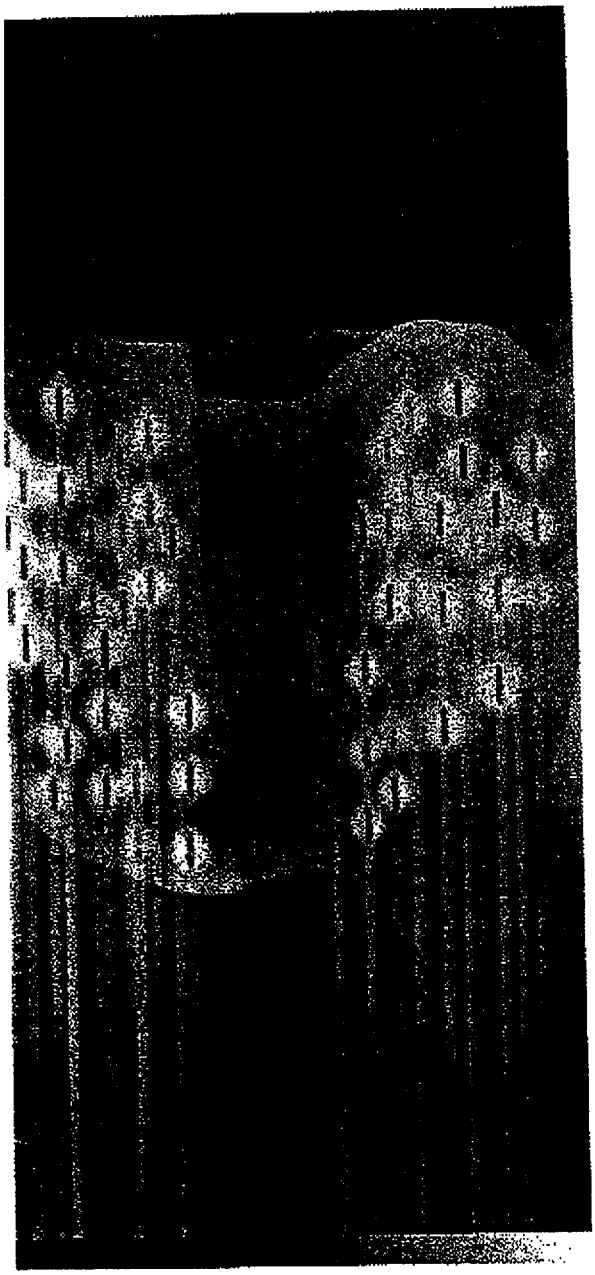
Quality Control: Armand **Date:** 8/2/99

Quality Assurance: RCH **Date:** 2 Aug 1999

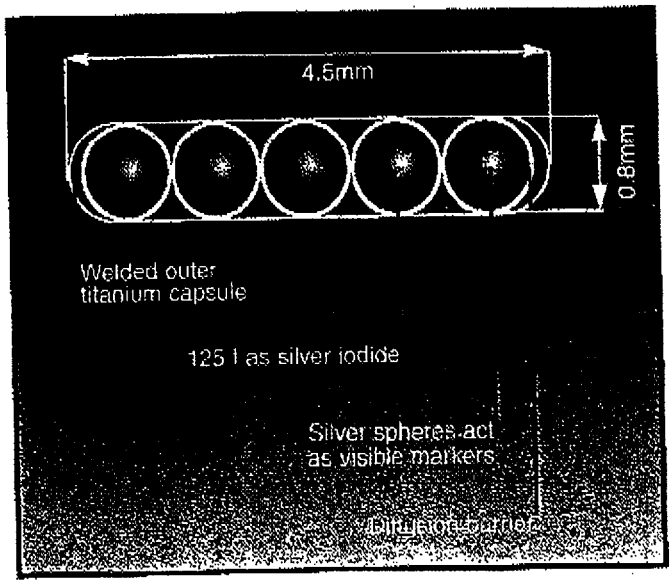
isoSTAR™

Iodine-125 Interstitial Seed

For Prostate Brachytherapy



- Visualization of location and orientation under all commonly used imaging modalities
- Silver spheres provide high contrast under x-ray and fluoroscopy
- Laser-welded outer titanium capsule
- Compatible with conventional brachytherapy needles and applicators
- 1999 NIST Air Kerma Standard traceable



Calibration

Each IsoSTAR™ Iodine-125 seed is measured by a detector that is calibrated by direct comparison against a standard source of the same model (i.e., identical configuration) which has been calibrated by the National Institute of Standards and Technology (NIST) utilizing the 1999 NIST Standard for Air Kerma Strength.

imagyn
MEDICAL TECHNOLOGIES

isoSTAR

Iodine-125 Interstitial Seed

TERMS AND CONDITIONS

Pricing

IsoSTAR™ I-125 .....$45.00 per seed
Calibration Seeds .....$60.00 per seed
Note: pricing is subject to change.

Cancellation Policy

Customers may cancel an order up until 12:00 noon CST ten (10) business days prior to scheduled shipment date.

Returned Goods Policy

IsoSTAR™ I-125
Customers must request a Returned Materials Authorization (RMA) number from Imagyn no later than 5 p.m. CST on the original scheduled surgery date, which is indicated on the Imagyn sales order confirmation. Customers must receive an RMA number before returning a product. IsoSTAR™ I-125 sources must be returned in their original unopened shipping container via overnight delivery. If required, Imagyn will provide customers with the appropriate shipping container. An RMA number and a return address can be obtained by calling Imagyn Customer Service at **(888) 242-7181**.
Note: Customers must pay for all shipping costs. A returned-materials-processing fee equal to 100% of the original invoice will be charged.

Freight and Handling Policy

All orders will be shipped FOB Denton, Texas. The freight & handling charge of $40.00 per shipment will be added to customers invoice.

Table 1

Apparent Activity In Millicuries	Air Kerma Strength (μGy m²/h)
0.28-0.30	0.36-0.38
0.31-0.33	0.39-0.42
0.34-0.36	0.43-0.46
0.37-0.39	0.47-0.50
0.40-0.42	0.51-0.53
0.43-0.46	0.55-0.58
0.47-0.50	0.60-0.64
0.51-0.54	0.65-0.69
0.55-0.59	0.70-0.75
0.60-0.64	0.76-0.81
0.65-0.69	0.83-0.88
0.70-0.75	0.89-0.95
0.76-0.81	0.97-1.03
0.82-0.88	1.04-1.12
0.89-0.96	1.13-1.22
0.97-1.04	1.23-1.32

Table 1 provides seed strength specifications in apparent activity and air kerma strength for some commonly used activities. To convert from apparent activity to air kerma strength multiply the activity by a factor of 1.27.

To Order Call Imagyn Toll Free At (888) 242-7181

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MEDICAL TECHNOLOGIES

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Manufactured for Imagyn Medical Technologies, Inc.
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