Checklist

APPENDIX C

Acceptance & Def. Checklist
John Jankovich 6/1/01

SUMMARY DATA

Name and Complete Mailing Address of the Applicant: Mills Pharmaceutical, Inc.	**Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:** Dr. Stanley Mills, 405 525-3141
The Applicant is (check one): [ ] Custom User [ ] Manufacturer [ ] Distributor [V] Manufacturer and Distributor	**If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:**
If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:	**Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:**
Model Number: Pd-103SL, Pd-103SH	**Principal Use Code (see Appendix F):** V
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.): brachytherapy seeds	**For Use by:** [✓] Specific Licensees Only [ ] General Licensees Only [ ] Both Specific and General Licensees [ ] Persons Exempt from Licensing
Leak-Test Frequency: [✓] Periodic Leak-Testing is Not Required [2] 6 Months [ ] Attached is justification for a leak test frequency of greater than 6 months	**Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):** 10 CFR 32.74 **Radionuclides and Maximum Activities (including loading tolerance):** Model P-103SH: 185 MBq (5 mCi) +10% Model P-103SL: 78 MBq (2.11 mCi) + 10%

CERTIFICATION:

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 AND 32 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 Name and Title

Signature:	**Date:**

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
DESCRIPTION/CONSTRUCTION		
If registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so?	OK	(seed dia: 0.5 ± 0.1 mm
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	Def	Cert. is dia 4.9 x 0.96 mm Amend dia 4.5 x 0.8
Assembly methods (screw, welds, etc.); verify integrity	OK	Seed dimensions are different Why?
Source mounting (size and integrity) and security	N/A	Pd seeds are surface coated by proprietary method, Need for further info?
Is source ANSI classification sufficient (from ANSI N542-1977):		All seeds have 5 silver spheres (instead of 3-5)?
Radiography - Unprotected 43515		
Radiography - In Device 43313		
Medical - Radiography 32312		
Medical - γ Teletherapy 53524		
γ Gauges - Unprotected 43333		
γ Gauges - In Device 43232		
β Gauges, Low Energy γ Gauges, or X-ray fluorescence 33222		
Oil Well Logging 56522		
Portable Moist/Density 43333		
Neutron Applications 43323	N/A	
γ Irradiators (II, III, IV) 43424		
γ Irradiators (I) 43323		
Static Eliminators 22222		
Smoke Detectors 32222		
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances	N/A	
On-Off indicators (description, qty., location)	N/A	
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	N/A	
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)	OK	
Shielding efficiency and integrity	N/A	
For medical devices: Was a 510(k) provided? (provide written notification to FDA)	Def	deficiency
Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991)	N/A	
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)	N/A	

I-125 max 5.55 GBq (150 mCi) + 10% clarify
Pd-103 max 185 MBq (5 mCi) + 10% "

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CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
LABELING		
Copy of label	OK	confirm that same as I-125
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	OK	
Permanent attachment and location(s) - visible to users?	OK	
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	OK	
CONDITIONS OF USE		
Expected working life of the source/device (years, operations)	Def	ask for useful life
Actions to be taken when product reaches end of its working life.	Def	" " disposal
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	Def	" " conditions
How the device will be used	OK	
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing		check this
PROTOTYPE TESTING/HISTORICAL USE	Def	
Tests methods and conditions (for source and device)	MBI	does not have historical experience w/ Pd-103
Tests results		
Years of use (incidents, failures, etc.)	MBI	does not refer to prototype tests w/ I-125 seeds
Similarities to other sources/devices if they are used as basis.		
RADIATION PROFILES		
Survey instrument used (type, window thickness, sensitivity, etc.)		rationale is OK: reduced specific γ rad constant reduced max activity
Conditions: including environments, scatter (product in beam), and use of guards and shields		
Distance from source/surface (per ANSI 538-1979)		
Shutter Open and Closed/Source Shielded		
Verify radiation surveys for γ radiation meet inv^2 law.		
Verify radiation surveys for non-γ radiation have not been calculated using inv^2 law.		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
QUALITY ASSURANCE		
Materials, subassemblies, services	OK	
Assembly methods (screws, welding, etc.)	OK	
Dimensions and tolerances	OK	
Activity, radiation levels, leak tests	Def	deficiency question: why is it reduced to 4 hrs from 18 hrs
QA Manual and comparison of manual to Regulatory Guide 6.9	OK	
INSTALLATION		
Fixed, portable, movable, fixed installation but portable source housing	N/A	
Inherent shielding, inaccessibility	N/A	
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers	N/A	
Mounting integrity	N/A	
SAFETY INSTRUCTIONS		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	Def	needs new instruction manual to include Pd-103
ACCOMPANYING DOCUMENTATION		
Leak tests results and radiation surveys	OK	
Transportation documents		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable	Def	
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations	N/A	

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION				OK/DEF	COMMENTS
SERVICING					
The following activities may be performed by the persons indicated:				N/A	
Activity	by a General Licensee	Only by a Specific Licensee	Will be Offered by the Applicant		
Installation					
Relocation					
Maintenance					
Repair					
Source Exchange					
Calibration					
Leak Testing					
Radiation Survey					
Training					
FOREIGN VENDORS					
Drop ship				N/A	
Who and where is source installed					
Leak test and radiation surveys					
QA in the U.S.					