Application and Review Checklist

The Application and Review Checklist are shown on the following pages.

SUMMARY DATA

Name and Complete Mailing Address of the Applicant:

DRAXIMAGE Inc.
16751 TransCanada Highway
Kirkland, QC
Canada, H9H 4J4

Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:

Dr. Richard J. Flanagan
Executive Vice-President
Tel: (514) 630-7039
Fax: (514) 694-9295
Email: rflanagan@DRAXIMAGE.com

The Applicant is (check one):

	Custom User
✔	Manufacturer
	Distributor
	Manufacturer and Distributor

If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:

(agent)
AAC Consulting Group
7361 Calhoun Place
Suite 500
Rockville, MD 20855

If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor: n/a

Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:

(distributor)
(800) 833-3533
Cytogen Corporation
600 College Road East
Princeton, NJ 08540

Model Number: BrachySeed ™ Pd-103 Model Pd-1

Principal Use Code (see Appendix F): (V) General Medical Use

Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):

Brachytherapy source

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
✔	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 35

Radionuclides and Maximum Activities (including loading tolerance): Palladium-103, 100 milliCuries (total maximum contained activity in a single source)

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: original signed by Dr. Richard Flanagan, Exec. VP **Date:** 4/24/2001

CHECKLIST

Registration Certificate Holder: DRAXIMAGE Inc.

Model: BrachySeed ™ Pd-103 Model Pd-1 source assembly

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?	NA	
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	OK	
Assembly methods (screw, welds, etc.); verify integrity	OK	
Source mounting (size and integrity) and security	NA	
Is source ANSI classification sufficient (from ANSI N542-1977): 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 γ Irradiators (II, III, IV) . . . . . 43424 γ Irradiators (I) . . . . . 43323 Static Eliminators . . . . . 22222 Smoke Detectors 32222	OK	ISO 2919-1999(E) recommended classification for Brachytherapy is C53211. This source tested to ISO/99/C53211.
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances	NA	
On-Off indicators (description, qty., location)	NA	
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	NA	
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)	OK	platinum and titanium
Shielding efficiency and integrity	NA	
For medical devices: Was a 510(k) provided? (provide written notification to FDA)	OK	510(k) #: K011119 BrachySeed Pd-103
Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991)	NA	
See “ANSI and Other Standards” list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)	OK	ISO 2919 ISO 9978

CHECKLIST

Registration Certificate Holder: DRAXIMAGE Inc.

Model: BrachySeed ™ Pd-103 Model Pd-1 source assembly

DESCRIPTION	OK/DEF	COMMENTS
LABELING		
Copy of label	OK	
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	OK	specified in RAI response
Permanent attachment and location(s) - visible to users?	OK	seeds labeled by package
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)	OK	six months, half-life limited
Actions to be taken when product reaches end of its working life.	OK	Disposal
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	OK	Use in hospital settings.
How the device will be used	OK	
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing	NA	
PROTOTYPE TESTING/HISTORICAL USE		
Tests methods and conditions (for source and device)	OK	
Tests results	OK	
Years of use (incidents, failures, etc.)	NA	new source
Similarities to other sources/devices if they are used as basis.	OK	very similar to DraxImage LS-1 iodine-125 source
RADIATION PROFILES		
Survey instrument used (type, window thickness, sensitivity, etc.)	NA	Monte Carlo calculation
Conditions: including environments, scatter (product in beam), and use of guards and shields	NA	
Distance from source/surface (per ANSI 538-1979)	OK	
Shutter Open and Closed/Source Shielded	NA	
Verify radiation surveys for γ radiation meet inv^2 law.	OK	
Verify radiation surveys for non-γ radiation have not been calculated using inv^2 law.	NA	

CHECKLIST

Registration Certificate Holder: DRAXIMAGE Inc.

Model: BrachySeed ™ Pd-103 Model Pd-1 source assembly

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	OK	
QA Manual and comparison of manual to Regulatory Guide 6.9	OK	
INSTALLATION		
Fixed, portable, movable, fixed installation but portable source housing	NA	
Inherent shielding, inaccessibility	NA	
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers	NA	
Mounting integrity	NA	
SAFETY INSTRUCTIONS		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	OK	package insert provided
ACCOMPANYING DOCUMENTATION		
Leak tests results and radiation surveys	OK	
Transportation documents	OK	
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable	OK	
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations	NA	

CHECKLIST

Registration Certificate Holder: DRAXIMAGE Inc.

Model: BrachySeed ™ Pd-103 Model Pd-1 source assembly

<table>
<tr><th colspan="4">DESCRIPTION</th><th>OK/DEF</th><th>COMMENTS</th></tr>
<tr><td colspan="4">SERVICING</td><td></td><td></td></tr>
<tr><td colspan="4">The following activities may be performed by the persons indicated:</td><td rowspan="11">OK</td><td rowspan="11">Source is a seed intended for implant into patients at licensed medical facilities. Damage seeds are not used. Seeds are not re-used.</td></tr>
<tr><td>Activity</td><td>by a General Licensee</td><td>Only by a Specific Licensee</td><td>Will be Offered by the Applicant</td></tr>
<tr><td>Installation</td><td></td><td>✔</td><td></td></tr>
<tr><td>Relocation</td><td>NA</td><td>NA</td><td>NA</td></tr>
<tr><td>Maintenance</td><td>NA</td><td>NA</td><td>NA</td></tr>
<tr><td>Repair</td><td>NA</td><td>NA</td><td>NA</td></tr>
<tr><td>Source Exchange</td><td>NA</td><td>NA</td><td>NA</td></tr>
<tr><td>Calibration</td><td>NA</td><td>NA</td><td>NA</td></tr>
<tr><td>Leak Testing</td><td></td><td>✔</td><td>✔</td></tr>
<tr><td>Radiation Survey</td><td></td><td>✔</td><td>✔</td></tr>
<tr><td>Training</td><td></td><td>✔</td><td></td></tr>
<tr><td colspan="4">FOREIGN VENDORS</td><td></td><td></td></tr>
<tr><td colspan="4">Drop ship</td><td>NA</td><td></td></tr>
<tr><td colspan="4">Who and where is source installed</td><td>OK</td><td></td></tr>
<tr><td colspan="4">Leak test and radiation surveys</td><td>OK</td><td></td></tr>
<tr><td colspan="4">QA in the U.S.</td><td>OK</td><td></td></tr>
</table>

William R. Ward
10/30/2001

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