

APPENDIX C

SUMMARY DATA

Name and Complete Mailing Address of the Applicant: <i>Novoste</i>		Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:	
The Applicant is (check one):		If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:	
<input type="checkbox"/>	Custom User		
<input type="checkbox"/>	Manufacturer		
<input type="checkbox"/>	Distributor		
<input checked="" type="checkbox"/>	Manufacturer and Distributor		
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:		Principal Use Code (see Appendix F):	
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):		For Use by:	
		<input checked="" type="checkbox"/>	Specific Licensees Only
		<input type="checkbox"/>	General Licensees Only
		<input type="checkbox"/>	Both Specific and General Licensees
<input type="checkbox"/>	Persons Exempt from Licensing		
Leak-Test Frequency:		Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):	
<input type="checkbox"/>	Periodic Leak-Testing is Not Required	Radiation Levels and Maximum Activities (including loading tolerance):	
<input checked="" type="checkbox"/>	6 Months		
<input type="checkbox"/>	Attached is justification for a leak test frequency of greater than 6 months.		

CERTIFICATION:

THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIALS 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?		only vary in # of sources contained
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)		✓
Assembly methods (screw, welds, etc.); verify integrity		OK
Source mounting (size and integrity) and security		N/A : sources contained, travel in catheter
Is source ANSI classification sufficient (from ANSI N542-1977):		Source has not been reviewed; will be treated as part of device
Radiography - Unprotected 43515		
Radiography - In Device 43313		
Medical - Radiography 32312		
Medical - ? Teletherapy 53524		
? Gauges - Unprotected 43333		
? Gauges - In Device 43232		
β Gauges, Low Energy ? Gauges, or X-ray fluorescence 33222		
Oil Well Logging 56522		
Portable Moist/Density 43333		
Neutron Applications 43323		
? Irradiators (II, III, IV) 43424		
? 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		interlocked dual connectors
On-Off indicators (description, qty., location)		one on device w/ indicators ; blink on low battery
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels		prevent retraction of sources, loss of sources out of catheter
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)		241 SS, Poly E, Poly Pro
Shielding efficiency and integrity		✓
For medical devices: Was a 510(k) provided? (provide written notification to FDA)		final notice pending from FDA
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.)		Source meets brachy. requirements

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Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
LABELING		
Copy of label		
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)		OK on device, transport case
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)		battery = 6 months, ~250 treatments
Actions to be taken when product reaches end of its working life.		
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)		source meet ISO 2919 C63241 device has additional trans. containers
How the device will be used		treatment of coronary artery disease
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing		N/A
PROTOTYPE TESTING/HISTORICAL USE		
Tests methods and conditions (for source and device)		dist will not handle (swap, new bats, etc)
Tests results		source ISO 8919 device: ISO/EN 60601-1 internal protection UL 2601-1 RD-510-007-10
Years of use (incidents, failures, etc.)		failures have been addressed response to NRC IN-98-10
Similarities to other sources/devices if they are used as basis.		MA
RADIATION PROFILES		
Survey instrument used (type, window thickness, sensitivity, etc.)		
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.	N/A	
Verify radiation surveys for non- γ radiation have not been calculated using inv^2 law.	✓	

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Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
QUALITY ASSURANCE		
Materials, subassemblies, services		ISO 9000 certification, EN qualified
Assembly methods (screws, welding, etc.)	✓	no welding; add-shaped head screws
Dimensions and tolerances	✓	provided
Activity, radiation levels, leak tests	✓	levels via calibration block, leak test performed
QA Manual and comparison of manual to Regulatory Guide 6.9	✓	ISO 9001 program; intensive QA manual directory
INSTALLATION		
Fixed, portable, movable, fixed installation but portable source housing		portable device w/ transport case
Inherent shielding, inaccessibility		shielded container (storage); multi. interlocks
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers		N/A - non-fixed gauge
Mounting integrity		N/A
SAFETY INSTRUCTIONS		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	✓	viz label, user's manual
ACCOMPANYING DOCUMENTATION		
Leak tests results and radiation surveys		
Transportation documents		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable		
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations	N/A	

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Registration Certificate Holder:

Model:

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