APPENDIX C

SUMMARY DATA

Name and Complete Mailing Address of the Applicant:	Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:
Novoste Corp 3890 Steve Reynolds Blvd Norcross, GA 30093	

The Applicant is (check one):		If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:
	Custom User	
	Manufacturer	
	Distributor	
X	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: Beta Cath System A1000 Series	Principal Use Code (see Appendix F): V - Medical

Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):	For Use by:	
IVB device	✓	Specific Licensees Only
		General Licensees Only
		Both Specific and General Licensees
		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):
	Periodic Leak-Testing is Not Required	
✓	6 Months	Radionuclides and Maximum Activities (including loading tolerance):
	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 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	different source train, sources similar
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	OK	
Assembly methods (screw, welds, etc.); verify integrity		not changed
Source mounting (size and integrity) and security	OK	jacketed train is better contained
Is source ANSI classification sufficient (from ANSI N542-1977): Radiography - Unprotected ..... 43515 Radiography - In Device ..... 43313 Medical - Radiography ..... 32312 Medical - ? Teletherapy ..... 53524 ? Gauges - Unprotected ..... 43333 ? Gauges - In Device ..... 43232 ß 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	OK	modified crush/impact test
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances		no changes
On-Off indicators (description, qty., location)		
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	OK	changed marker ~~source~~ material of construction relocate sensor for jacketed source train
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)		no changes
Shielding efficiency and integrity	OK	
For medical devices: Was a 510(k) provided? (provide written notification to FDA)		PMA received or in process (refer to limit/consist in cert.)
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.)		

APPENDIX C

CHECKLIST

Registration Certificate Holder:

Model:

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	only text changed on storage container label
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)	OK	trying to increase battery life
Actions to be taken when product reaches end of its working life.	OK	return to mnfr
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	OK	not changed
How the device will be used		IVB, coronary & other arteries in stent test.
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)		new source OK
Tests results		↓
Years of use (incidents, failures, etc.)		
Similarities to other sources/devices if they are used as basis.	OK	test
RADIATION PROFILES		
Survey instrument used (type, window thickness, sensitivity, etc.)		
Conditions: including environments, scatter (product in beam), and use of guards and shields		not changed
Distance from source/surface (per ANSI 538-1979)	OK	
Shutter Open and Closed/Source Shielded	OK	
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.		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
QUALITY ASSURANCE		
Materials, subassemblies, services		not changed – same applies
Assembly methods (screws, welding, etc.)		
Dimensions and tolerances		
Activity, radiation levels, leak tests		
QA Manual and comparison of manual to Regulatory Guide 6.9		
INSTALLATION		
Fixed, portable, movable, fixed installation but portable source housing		not changed
Inherent shielding, inaccessibility		
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers		
Mounting integrity		
SAFETY INSTRUCTIONS		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	OK	
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	N/A	

CHECKLIST

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				
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.					

no changes