From: John Jankovich
To: TSK
Date: Wed, Aug 11, 1999 10:30 AM
Subject: Case 99-44 acceptance review

Traci
I completed the acceptance review of #99-44, MDS Nordion for their TheraSphere device. It is acceptable. J.J.

CC: FCS, MLB5

Acceptance Review 8/11/99 J.J.

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:
MDS Nordion	Ann Wachnik Cenone 613 592-3400

The Applicant is (check one):		If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:
	Custom User	X2033
	Manufacturer	
	Distributor	
✓	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: TheraSphere	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.): ~~therapeutic seeds~~ glass microspheres	For Use by:
	✓ Specific Licensees Only
	General Licensees Only
	Both Specific and General Licensees
	Persons Exempt from Licensing

Leak-Test Frequency: N/A	Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5): 10 CFR 35
Periodic Leak-Testing is Not Required	
6 Months	Radionuclides and Maximum Activities (including loading tolerance): Y-90
Attached is justification for a leak test frequency of greater than 6 months	20 GBq (540 mCi) per dose

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:

Bob Phillips/FDA

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?	✓	
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	✓	
Assembly methods (screw, welds, etc.); verify integrity		no welding info
Source mounting (size and integrity) and security	✓	
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	N/A	
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.)	N/A	
Shielding efficiency and integrity	✓	
For medical devices: Was a 510(k) provided? (provide written notification to FDA)		pending
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.)		ISO-2919-1998

CHECKLIST

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)		no material/dimension
Permanent attachment and location(s) - visible to users?	✓	
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	✓	
CONDITIONS OF USE		
Expected working life of the source/device (years, operations)	✓	
Actions to be taken when product reaches end of its working life.		not specified
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)		not provided
How the device will be used	✓	
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)	✓	
Tests results	✓	
Years of use (incidents, failures, etc.)	✓	
Similarities to other sources/devices if they are used as basis.	N/A	
RADIATION PROFILES		
Survey instrument used (type, window thickness, sensitivity, etc.)		not specified
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	N/A	
Verify radiation surveys for γ radiation meet inv^2 law.	~~✓~~	B
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		
Assembly methods (screws, welding, etc.)		
Dimensions and tolerances		no mfr QA
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		
Inherent shielding, inaccessibility		administration as described
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		transp. info provided
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		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION				OK/DEF	COMMENTS
SERVICING				N/A	
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					
Relocation					
Maintenance					
Repair					
Source Exchange					
Calibration					
Leak Testing					
Radiation Survey					
Training					
FOREIGN VENDORS				✓	MDS Nordion is quasi US
Drop ship					
Who and where is source installed					
Leak test and radiation surveys					
QA in the U.S.					