



Science Advancing Health

August 13, 1999

John T. Yankovich Senior Engineer
Office of Nuclear Materials Safety and Safeguard
United States Nuclear Regulatory Commission
Mail Stop: T-8F-5 2 White Flint North
11545 Rockville Pike
Rockville, MD
20555

Dear Mr. Yankovich:

RE: TheraSphere Application for USNRC Sealed Source and Device Registration

Further to our telephone conference call on August 11, 1999, concerning the MDS Nordion application to the US NRC for sealed source and device registration for TheraSphere, the following additional information and comments are provided and addressed for your review:

1. **Provide a copy of the registration to meet the requirements of ISO 9001.**

Response:

See attachment 1: ISO 9001 registration.

2. **Provide a copy of the MDS Nordion quality program.**

Response:

See attachment 2: Nuclear Medicine Quality Manual.

3. **Please provide information to show that the test specimens used in 1993 to leach analysis are of the same composition as the product currently manufactured.**

Response:

The article "Chemical durability of Y_2O_3 - Al_2O_3 - SiO_2 glasses for the in vivo delivery of beta radiation, J. Biomed. Materials Res. 27:1301-1308, 1993 provided the following information:

The most durable composition of YAS in the above reference is YAS-4 frit. The % mol stated for this formulation is 17% Y_2O_3 , 19% Al_2O_3 and 64% SiO_2 . The molar mass of these compounds is Y_2O_3 226 g/mol, Al_2O_3 102 g/mol and SiO_2 60 g/mol.

	g/mol	% mol	total mass	mass %
Y_2O_3	226	17	3842	40
Al_2O_3	102	19	1938	20
SiO_2	64	64	3840	40

The above formulation is the same mass % formula which MDS Nordion uses in the manufacture of their glass frit and which is subsequently made into spheres. The specification for the glass frit (990601.SPE) which references the purity of the glass and this information is cross-reference in the specification for glass microspheres (990602.SPE).

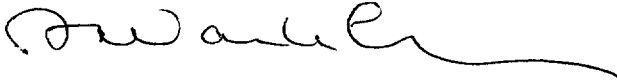
4. Provide a copy of ISO 2919.

Response:

See attachment 4: ISO 2919

Please do not hesitate to contact me if additional clarification is required. Thank you for the quick attention given to our application. It is much appreciated.

Yours sincerely,



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