UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 23, 1999

Ms. Ann Warbick Cerone
Manager, Regulatory Affairs
MDS Nordion
447 March Road
Kanata, Ontario, Canada
K2K 1X8

Dear Ms. Cerone:

This letter is in response to your application dated July 2, 1999, and your letter dated August 13, 1999, requesting registration of your Model TheraSphere device under the provisions of 10 CFR 32. We are in the process of evaluating your request. In order to continue our evaluation, we need additional information on the following issues:

1. Provide a drawing, showing the major dimensions, for the "12 mm lucite vial shield" and its closure (as described on page 2 and shown in Figure 1 of the application). The drawing should also illustrate the cavity for the glass vial containing the microspheres.

2. Provide a drawing, showing the major dimensions, for the lead shield in which the lucite vial is stored and transported. The drawing should illustrate the cavity for the lucite container. An assembly drawing for Items 1 and 2 is also acceptable if it displays the information which we request.

3. Regarding labeling, please specify

   a. the material, thickness and adhesive characteristics of the label which you intend to use on the lead-pot/lucite-shield (page 7 of the application);

   b. the handling and storing instructions as required by 10 CFR 32.74 (a)(2)(viii);

   c. how you will designate the activity level as required by 10 CFR 32.74 (a)(3).

4. Specify if you use serial numbers to identify each TheraSphere dose. If yes, please indicate where the serial number is located and how durable the identification is. If no, describe why individual dose identification is not needed.

5. Regarding prototype testing, we understand that testing of individual microspheres has not been performed by MDS Nordion, due to the limitations of their microscopic size. Therefore, please provide historical data on the TheraSphere devices (i.e. microspheres in the lucite container) that have been manufactured over the years and used in other countries. Specify how many years they have been in use and what accident conditions they have survived. State that the products are identical in size and construction, and whether or not problems have been encountered in transportation, handling and in clinical practice.

6. Provide prototype test information on the lucite shield and its closure illustrating transportation accidents and accidental drops likely to be encountered during storage and use. For example, you may show how it retains its content if dropped from a height of 1 m to a typical hospital floor.

7. Regarding external radiation levels, NRC needs information on the device itself, not on the radiation levels around the patient as addressed in the application. Therefore, please specify:

   a. External radiation levels around the lucite vial containing the maximum dose of 20 GBq (540 mCi). Provide the data , preferably, at the surface, and at 5, 30 and 100 cm. If there are no meaningful readings at these locations, please state so.
   b. Provide similar external radiation levels, if any, outside the lead pot with the lucite vial inside containing a maximum dose of microspheres.
   c. Please specify the instrumentation which you used to perform the radiation profile measurements by listing the instrument manufacturers, model numbers, calibration dates, sensitivity, etc.
   d. Provide the annual occupational dose rate to personnel administering the microspheres. Base your calculation on how many administrations a person would likely complete in a year, how much the activity level in a kit could be on the average, and on how long each procedure would take. In your response, please describe the assumptions on which you base your calculations.

8. Procedure No. 990602.SPE refers to Yttrium-89. Specify that it applies to Yttrium-90 used in the manufacture of the microspheres for the TheraSphere device.

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the resubmission of a complete application.

Please also note that NRC cannot issue a registration of your device until FDA has approved it for medical use in this country. Therefore, please send us a copy of Form 510k when you receive it.

If you have any questions, please contact me at (301) 415-7904 or Dr. Seung Lee at (301) 415-5788.

Sincerely,

/S/

John P. Jankovich, Ph.D., Sr. Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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