



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

April 2, 2002

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

**SUBJECT: REQUEST FOR WITHHOLDING INFORMATION FROM PUBLIC DISCLOSURE,  
MDS NORDION MODEL THERASPHERE DEVICE**

Dear Ms. Cerone:

By MDS Nordion's (Nordion's) application dated September 6, 2001, your letter dated March 1, 2002, and your affidavit dated March 4, 2001, Nordion submitted an application for registration of the Model TheraSphere microspheres. Nordion has requested that 32 engineering drawings, listed in the letter dated March 1, 2002, be withheld from public disclosure pursuant to 10 CFR 2.790.

Nordion stated that these drawings should be considered exempt from mandatory public disclosure for the following reasons:

1. The disclosure of the information contained in the drawings would cause irreparable harm to Nordion. In particular, these drawings contain information, developed by Nordion with Nordion's resources regarding specifications such as manufacturing specifications, references to fabrication methods, acceptance/rejection tolerances for components.
2. Release of this information to third parties would enable and assist third parties to use such information to fabricate and register a similar device without incurring any development cost.
3. Disclosure of the information would compromise Nordion's ability to compete in the marketplace.
4. The information is held in confidence by Nordion and its vendors and any disclosure of the information contained in the drawings has been accompanied by a confidentiality agreement protecting the trade secrets therein.

5. The information is not available in public sources.

We have reviewed Nordion's application and the engineering drawings in accordance with the requirements of 10 CFR 2.790 and, on the basis of your statements, have determined that the submitted information sought to be withheld contains proprietary commercial information.

Therefore, the drawings listed as proprietary, will be withheld from public disclosure pursuant to 10 CFR 2.790(b)(5) and Section 103(b) of the Atomic Energy Act of 1954, as amended.

Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, we may send copies of this information to our consultants working in this area. We will, of course, ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future such that the information could then be made available for public inspection, you should promptly notify the NRC. You also should understand that the NRC may have cause to review this determination in the future, for example, if the scope of a Freedom of Information Act request includes your information. In all review situations, if the NRC makes a determination adverse to the above, you will be notified in advance of any public disclosure.

Sincerely,

/RA

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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