

Amend NR-0220-D-113-S to
Replace the Monarch 25 Syringe

MDS Nordion application dated September 15, 2004, contains insufficient information. "Consolidated Guidance About Materials Licenses: Application for Sealed Source and Device Evaluation and Registration," NUREG-1556, Vol. 3, Rev. 1 provides guidance on sealed source and device related issues. The document is available at the NRC web-site: www.nrc.gov.

1. Description/Construction:

Please provide specifications and description for the inflation syringe, including materials and dimensional compatibility with the catheters. In addition, please provide the minimum requirements of the syringe in order to assure proper functioning with the MDS Nordion delivery system for yttrium-90 therspheres. Confirm that MDS Nordion will only supply syringes that meet the minium requirements.

2. Prototype Testing:

Please provide the operational history of the syringes that MDS Nordion proposes to supply, if any, please indicate how many units have been distributed, how long have they been in use, and failures if any, in normal use or accident conditions.

3. Quality Assurance Program

Please confirm that you have not modified your quality assurance program you previously submitted and referenced in your application. Please indicate whether the Certificate Number Q15066 referenced in your previous application is still valid.

Enclosure

December 1, 2004

Marc-André Charette
Manager, Regulatory Affairs
MDS Nordion
447 March Road
Ottawa, ON K2K 1X8
Canada

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION ON AMENDMENT FOR GLASS
MICROSPHERE (NR-0220-D-113-S)

Dear Mr. Charette,

This letter is in response to your application dated September 15, 2004 for an amendment to the sealed source registration NR-0220-D-113, Glass Microsphere. In reviewing your application, we find that it is lacking required information. In the Enclosure of this letter, we have summarized the issues not addressed in your application.

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 submission of a complete application.

If you have any questions, please contact me at (301) 415-7138 or Mr. Ujagar S. Bhachu at 301-415-7894.

Sincerely,

/RA/

Tomas Herrera, Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

cc: DBHowe, MSIB-B

Distribution:

MSIB r/f IMNS r/f SSD-04-56

File Name: E:\Filenet\ML043360069.wpd

ML043360069

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	MSIB	E	MSIB	E	MSIB	E			
NAME	THerrera /RA/		UBhachu /RA/		JJankovich /RA/				
DATE	11/1/04		11/4/04		12/1/04				

OFFICIAL RECORD COPY

December 1, 2004

Marc-André Charette
Manager, Regulatory Affairs
MDS Nordion
447 March Road
Ottawa, ON K2K 1X8
Canada

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION ON AMENDMENT FOR GLASS
MICROSPHERE (NR-0220-D-113-S)

Dear Mr. Charette,

This letter is in response to your application dated September 15, 2004 for an amendment to the sealed source registration NR-0220-D-113, Glass Microsphere. In reviewing your application, we find that it is lacking required information. In the Enclosure of this letter, we have summarized the issues not addressed in your application.

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 submission of a complete application.

If you have any questions, please contact me at (301) 415-7138 or Mr. Ujagar S. Bhachu at 301-415-7894.

Sincerely,

/RA/

Tomas Herrera, Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated
cc: DBHowe, MSIB-B