



December 6, 2001

Mr. William R. Ward
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
Mail Stop: T-8F5
United States Nuclear Regulatory Commission
Two White Flint North
11545 Rockville Pike
Rockville, MD
20852-2738

RE: Sealed Source Registration for MDS Nordion Haan, GammaMed 212

Dear Mr. Ward:

Thank-you for the Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Sealed Source for the GammaMed 212 source number NR-0220-S-124-S and the amended registration for the GammaMed 12i/12it device number NR-0220-D-121-S. MDS Nordion reviewed both registration and would like to request the following modifications:

GammaMed 12i/12it Registration number NR-0220-D-121-S

1. RE: Page 4 of 16, second paragraph starting with, "The dummy source can also be used to verify actual source position as compared to programmed source position."
The last line in the reference should be changed to "(see Attachment 6)". Hence the sentence should be revised to read, "As an additional check, the actual position of the live source can also be viewed (remotely) using this adapter (see Attachment 6)."
2. RE: Page 10 of 16, item 4, "A stainless steel source identification which is supplied with the source assembly."
MDS Nordion would like to add aluminum foil as an alternate material for the source identification plate. Hence the sentence should be revised to read, "A stainless steel or aluminum foil identification which is supplied with the source assembly."

GammaMed 212 Registration number NR-0220-S-124-S

1. RE: Page 2 of 9 last paragraph starting with, "The source capsule measures 1.1 mm (0.043 inches) in diameter and 4.6 mm (0.181 inches) in length."
For clarification the source capsule without the cap measures 4.6 mm in length. Therefore, the sentence should be revised to read, "The source capsule without the cap measures 1.1 mm (0.043 inches) in diameter and 4.6 mm (0.181 inches) in length."
2. RE: Page 3 of 9 second paragraph under labelling starting with, "A stainless steel source identification label is provided with each source assembly for attachment to the device in which the source assembly will be installed."
As mentioned above, MDS Nordion would like to add aluminium foil as an alternate material for the source identification plate. Hence the sentence should be revised to read, "A stainless steel or aluminium foil source identification label is provided with each source assembly for attachment to the device in which the source assembly will be installed."
3. RE: Page 7 of 9 the second paragraph starting with, "The attachment of the source capsule to the cable is tested for proper attachment."
As mentioned in my letter of August 30, 2001, the tensile force applied to the attachment of the source capsule to the cable during the MDS Nordion S.A. manufacturing process will be 40 Newtons for a period of ten seconds. In addition, the tensile force applied immediately after welding the cap to the capsule is 15 Newtons for 10 seconds. Hence, to cover both the Mallinckrodt and MDS Nordion S.A. manufacturing process the following paragraph is suggested:
"All welds including the attachment of the source capsule, the connector to the cable and the cable assembly are tested for proper attachment. A tensile load of at least 40 Newtons (9 lbf) is applied to this attachment for a minimum of ten seconds. In addition, immediately after welding the cap to the capsule a 15 Newtons (3.4 lbf) force is applied for a minimum of 10 seconds."
4. RE: Page 7 of 9 the third paragraph starting with, "A minimum of 5% of a cable assembly production batch is separated for further testing."
It should be noted that the cable weld test done by Mallinckrodt is different from the one done by MDS Nordion S.A. Mallinckrodt does not have the tooling to do the load cycle test but they do a microscopic examination and a destructive tensile test on every 25th cable weld. On the other hand MDS Nordion S.A. can do the cycle test and the microscopic examination. Hence to cover both the Mallinckrodt and MDS Nordion S.A. manufacturing process the following paragraph is suggested:
"A minimum of 4% of a cable assembly production batch is separated for further testing of the rigid to flexible cable weld. Each of these cable assemblies is subjected to either a loaded cycle test with a microscopic examination or a microscopic examination with a destructive tensile test as

described below. The production batch is rejected if one or more cable assemblies fails the required tests.

Loaded cycle test: The cable weld passes four times through two 180-degree bends, which are each 10 mm (0.4 in) radius, while under a tensile load of 50 Newtons (11.2 lbf).

Microscopic examination: The weld is sectioned and microscopically examined to determine the integrity of the interior of the cable and the integrity of the welding.

Destructive tensile test: The cable assembly must withstand a destructive tensile of greater than 90 Newtons (20.3 lbf).”

If you have any questions or require further information please feel free to contact me by telephone at (613) 592-3400 extension 2421 or by email at mcharette@mds.nordion.com.

Yours sincerely

A handwritten signature in black ink, reading "Marc-André Charette". The signature is written in a cursive style with a long horizontal stroke at the end.

Marc-André Charette
Regulatory Affairs Senior Associate

Copy to: Ann Warbick Cerone, MDS Nordion
Scott McIntosh, David Gill, MDS Nordion
Dr. Wolfgang Nuding, Jurgen Handke MDS Nordion Haan
Véronique Meurisse, MDS Nordion S.A.