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MDS Nordion
Science Advancing Health

November 5, 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:

Please find attached the additional information requested in your e-mail of November 2, 2001, to Ms. Ann Warbick Cerone.

1. For question 3, we did receive an English translation of the procedure, but not the one page drawing, WQ2-001, which we understood to be integral to the procedure. Please provide the English translation of the drawing.

   The English translation of Drawing WQ2-001 was provided by email on November 2, 2001.

2. Questions 1.a, 1.c, 1.d, 4.a, 4.b, and 4.c all concerned labelling. Specifically, questions 1.a and 4.a concerned the name at the top of the source label. In your application, your example says, "MDS Nordion Haan GmbH," the name of the manufacturer. However, this must be the name of the distributor. Please change the source label to have the name of the distributor, not the manufacturer.

   The manufacturers name, "MDS Nordion Haan, GmbH" is listed on top of the source label since these sources are distributed in Europe, Canada, the United States and other locations across the world. MDS Nordion, Kanata is the distributor only for the sources sold in Canada and the United States. Instead of changing the source label, MDS Nordion will affix to the top of the device a new label (attachment 1) which will include the words, "Device and source are

distributed by: MDS Nordion, Kanata, Canada." The label material for the new label will be stainless steel. The new label will be affixed to the top of the device.

3. Questions 1.c, 1.d, 4.b, and 4.c concerned labelling required by 10 CFR 32.74. This affects the permanent labelling on the device itself. Your current labelling does not provide the required information and your response did not adequately explain how this information would be provided. You will need to either replace your device's current labelling or add a new label to meet the requirements.

   We will accept referencing the User's Manual, or the Source Installation procedure, for the details of the information required by 10 CFR 32.74 (a)(2)(viii), as long as the new label directed the device user to the manual/procedure for this information. In this case, the section of the manual you provided in your response did not give the information required by 10 CFR 32.74 (a)(2)(viii). Therefore, you will need to update the manual and provide users a new label for the device to reference the manual.

   MDS Nordion will affix to the top of the device a new label (attachment 1) which will include the words, "Instructions for handling and storing the source or device from a radiation safety standpoint can be found in the GammaMed 12i/12it User's Manual." The label material for the new label will be stainless steel. The new label will be affixed to the top of the device.

   Storage and handling instructions are currently located in various sections of the User's Manual. As requested by the USNRC a separate annex will be added to the User's Manual, which will specifically address the storage and handling instructions. Current owners of the GammaMed 12i/12it will be provided with this annex. This annex will be appended to manuals for new owners.

4. The new label must have the information required by 10 CFR 32.74 (a)(3).

   MDS Nordion will affix to the top of the device a new label (attachment 1) which will include the words, "The U.S. Nuclear Regulatory Commission has approved distribution of the GammaMed device and source contained herein to persons licensed to use by product material identified in §§ 35.57, 35.400, or 35.500, as appropriate, and to persons who hold an equivalent license issued by an Agreement State." The label material for the new label will be stainless steel. The new label will be affixed to the top of the device.

5. We understand that there are existing devices in use which would not be able to have a new label immediately installed. In our conversation on November 2, 2001, Ann Warbick Cerone of MDS Nordion and William Ward of NRC discussed a possible system whereby MDS Nordion would distribute the new label, with explicit instructions on where it was to be installed on the device, with newly issued sources. You would also need to distribute the updated User's Manual. Since the GammaMed

212 will be the only source available for the device, this distribution system would ensure that within 6 months to a year, all devices in use would have the new label and updated User's Manual. All newly distributed devices would have the label installed and be distributed with the new User's Manual.

Therefore, we request that you provide an example of the new label, a copy of the instructions on where it would be mounted, a copy of the referenced User's Manual section or Installation Procedure, and confirm how and when you will ensure that the new label is installed on existing devices.

The new label will be affixed during a source change service call. This will occur during the next 6 months to one year. The new label and instructions for affixing the label will be provided with the source shipment or in the case of an MDS Nordion service technician, the label and instructions will be carried to the site. The draft label is shown in attachment 1 and the Instructions for Affixing the label is shown in Attachment 2.

As indicated in our response to Comment 3, the Handling and Storage Annex of the User's Manual will be provided to current users and appended to manuals for new users.

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

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

Attachment 1

Draft Label

This is an example of the suggested wording for a new label to be affixed to the GammaMed 12i/12it.

Device and Source distributed by:
MDS Nordion, Kanata, Canada

The U.S. Nuclear Regulatory Commission has approved distribution of the GammaMed device and source contained herein to persons licensed to use by product material identified in §§ 35.57, 35.400, or 35.500, as appropriate, and to persons who hold an equivalent license issued by an Agreement State.

Storage and Handling

Instructions for handling and storing the source or device from a radiation safety standpoint can be found in the GammaMed 12i/12it User's Manual

Attachment 2

INSTRUCTIONS FOR APPLICATION OF NEW LABEL ON THE GAMMAMED DEVICE

Pursuant to requirements of the United States Nuclear Regulatory Commission (US NRC) the attached label must be affixed to the top of the GammaMed 12i/12it devices during source replacement.

Device and Source distributed by:
MDS Nordion, Kanata, Canada

The U.S. Nuclear Regulatory Commission has approved distribution of the GammaMed device and source contained herein to persons licensed to use by product material identified in §§ 35.57, 35.400, or 35.500, as appropriate, and to persons who hold an equivalent license issued by an Agreement State.

Storage and Handling
Instructions for handling and storing the source or device from a radiation safety standpoint can be found in the GammaMed 12i/12it User's Manual

Following this procedure, please complete and sign this form below and return to:

Mr. Dan Doucett
MDS Nordion
447 March Road
Kanata, Ontario,
Canada K2K 1X8
Fax: (613) 591-6077 or (613) 591-2142

Installation Site/Address: _____

Device Model and Serial No. : _____

Service Technician: Print Name _____

Signature_____

Date: _____