From: William Ward <WRW1@nrc.gov>
To: "WARBICK CERONE, Ann (Kanata)" <AWARBICK@MDS.Nordion.com>, "CHARETTE, Marc-Andre (Kanata)" <MCHARETTE@MDS.Nordion.com>
Date: 11/02/2001 11:35:27 AM
Subject: Follow-up to MDS Nordion response of 10/23/2001

Mr. Charette,
Ms. Warbick Cerone,

We received your 26 page faxed response to our questions, and the 2 page English translation of the procedure PA M0020e, revision 4. We find the responses to questions 1.b, 1.e, and 2 are acceptable. 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.

Questions 1.a, 1.c, 1.d, 4.a, 4.b, and 4.c all concerned labeling. 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.

Questions 1.c, 1.d, 4.b, and 4.c concerned labeling required by 10 CFR 32.74. This affects the permanent labeling on the device itself. Your current labeling 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 labeling 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.

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

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.
Sincerely,

William R. Ward, P.E.
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CC: "SHORKEY, Ruth (Kanata)" <RSHORKEY@MDS.Nordion.com>, John Jankovich <JPJ2@nrc.gov>, Seung Lee <SJL@nrc.gov>

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From: William Ward <WRW1@nrc.gov>

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