

From: William Ward
To: internet:MCharette@MDS.Nordion.com
Date: 8/29/01 5:18PM
Subject: GammaMed 212 source registration questions

Mr. Charette,

We are nearing completion of our review of your application for registration of the GammaMed 212 source. As part of the review, we have developed several questions or requests. They are listed below. Please respond to these question via letter, email or fax. Our fax number is (301) 415-5369. If you have any questions concerning these, you may phone me at the number provided below. Thank you very much.

1. In section 9, Quality Assurance and Control, you stated that a tensile load of 60 Newtons (13.5 pounds) is applied to test the attachment of the source capsule to the cable. Please provide the length of time that this stated force is applied.
2. For comparison to the testing force mentioned in question 1 above, please provide the maximum tension which can be applied by the GammaMed 12i/12it device which you intend to use this source in.
3. Please provide a copy of the current ISO 9001 certificates for both MDS Nordion in Canada, and MDS Nordion Haan GmbH. The copy of the certificate previously provided expired in May 2001.
4. The FDA clearances you received for the GammaMed 12i and 12it devices appear to have been based on use of the device with the currently approved source for the device, a CIS-US Inc. model 724. Please provide documentation showing that these FDA clearances have been updated to include the GammaMed 212 source.

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Creation Date: 8/29/01 5:18PM

From: William Ward

Created By: WRW1@nrc.gov

Recipients	Action	Date & Time
MDS.Nordion.com	Transferred	08/29/01 05:19PM
MCharette (internet:MCharette@MDS.Nordion		

Post Office	Delivered	Route
MDS.Nordion.com		internet

Files	Size	Date & Time
MESSAGE	2572	08/29/01 05:18PM

Options

Auto Delete: Yes
Expiration Date: 9/28/01
Notify Recipients: Yes
Priority: Standard
Reply Requested: No
Return Notification: None

Concealed Subject: No
Security: Standard

To Be Delivered: Immediate
Status Tracking: All Information