

**From:** William Ward  
**To:** Marc-Andre Charette  
**Date:** 10/18/01 12:05PM  
**Subject:** GammaMed 212 and 12i, 12it additional questions

Mr. Charette,

I apologize for asking for more information. However, my follow-up reviewer has noted some aspects of the regulations which have not yet been fulfilled. He also has an additional couple of questions. 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.

For the GammaMed 212 source:

1. LABEL

- a. The source identification label has German manufacturer name. It should be the Canadian distributor name (please see NUREG-1556, Vol. 3, page 10-9).
- b. What is the source identification label material?
- c. Per 10 CFR 32.74(a)(2)(viii), the label should have instructions for handling and storing the source from the radiation safety standpoint.
- d. Per 10 CFR 32.74(a)(3), the label should have a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source) to persons licensed to use byproduct 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.
- e. Are words on the stainless end cap etched or engraved? Section 2 of the application, Construction of the Sealed Source, fourth paragraph says it is etched, however, the NUREG-1556, volume 3 checklist you provided says it is engraved.

2. PROTOTYPE TESTING

- a. Your prototype testing reports verifying the ANSI 43.6-1997 Classification as 97C63322 indicate that the contents of the test sources were iridium pellets. However, no radioactivity level is specified. What was the activity of the source capsules which were tested?

3. ADMINISTRATIVE

- a. Please provide an English version for the attachment in 10/16/01 letter concerning cable bending.

For the GammaMed 12i/12it device:

4. LABEL

- a. The source identification label has German manufacturer name. It should be the Canadian distributor name (please see NUREG-1556, Vol. 3, page 10-9).
- b. Per 10 CFR 32.74(a)(2)(viii), the label should have instructions for handling and storing the device from the radiation safety standpoint.
- c. Per 10 CFR 32.74(a)(3), the label should have a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of device) to persons licensed

to use byproduct 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.

Sincerely,

William R. Ward, P.E.  
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**Subject:** GammaMed 212 and 12i, 12it additional questions  
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**From:** William Ward

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MDS.Nordion.com MCHARETTE (Marc-Andre Charette)	Transferred	10/18/01 12:06PM

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