

ENCLOSURE

We are in the process of reviewing your application for the Model C-198 irradiator source. In order to continue our review, we need the following information:

1. Please conform that we could use the Technical Illustration drawing IN/SS 1255 C198, Issue 6 for the C-198 sealed sources in the Attachment for the registration certificate.
2. Please provide the following drawings:
 - a. diameter and thickness, with their tolerances for the outer cylinder
 - b. length, diameter, and thickness, with their tolerances for the inner cylinder
 - c. complete drawings for end caps for inner and outer cylinders, and spacers
3. Please clarify the following:
 - a. for Co-60 slug diameter, DCN A1540-D06-A shows 6.35 mm, however, CDN/0014/S-85, Rev. 2, shows 6.3 mm.
 - b. for outer cylinder maximum diameter, G530102-140 shows 9.8 mm, however, DCN A1540-D06-A shows 9.73 mm.
 - c. for outer cylinder maximum length, G530102-140 shows 210.0 mm, however, DCN A1540-D06-A shows 209.9 mm.
4. Please provide the weld information which was referred to on the left hand side in Drawing No. 530102-140.
5. The maximum activity increases from 3500 Ci to 5000 Ci. Please provide the increases for temperature, thermal stresses on inner and outer cylinders, and on welds at end caps due to the activity increase.
6. For the prototype testing:
 - a. The source certification sheet listed that Co-60 slugs were used. Were active sources used in the tests? If so, please provide the actual activities used for the testing. If not, please describe the slugs.
 - b. Provide the diameter for the 2 kg mass used in impact testing.
 - c. The resonant search using the Data Physics controller was unsuccessful. Then, how are the natural frequencies of 472 and 39 Hz determined?
 - d. Please provide the characteristics of the pin used in the puncture test.
7. Please provide a copy of ISO 9001 certificate.
8. Please specify the "Conditions of Use" for sources that are to be used in Panoramic, Dry Storage Gamma Irradiators (Category II), page 3, ¶2, in your application.
9. Please specify in what Models of Category II irradiators were the C-198 sealed sources designed to be used.

Marc-André Charette
Regulatory Affairs Senior Associate
MDS Nordion
447 March Road
Kanata, Ontario
Canada, K2K 1X8

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION ON MODEL C-198

Dear Mr. Charette:

This letter is in response to your application dated December 14, 2000, requesting sealed source and device evaluation and registration of your C-198 source. We are in the process of evaluating your request. In order to continue our evaluation, we need additional information attached in the Enclosure.

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application.

If you have any questions, please contact me at (301) 415-5787 or Dr. John Jankovich at (301) 415-7904.

Sincerely,

/RA/

Seung J. Lee, Mechanical Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

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January 16, 2001

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