Enclosure

Additional Information for
an Amendment to NR-0220-S-112-S
Radiographic Source Assembly, Model: C-337A

MDS Nordion application dated June 13, 2003, contained insufficient information on the issues below. Guidance on addressing the issues may be found in "Consolidated Guidance About Materials Licenses: Application for Sealed Source and Device Evaluation and Registration," NUREG-1556, Vol. 3. The document is available at the NRC web-site: www.nrc.gov.

1. Description/Construction:

   1.1 Confirm that the same physical dimensions and construction will be used.

   1.2 Confirm that the ANSI classification is the same.

2. Labeling:

   2.1 Confirm that the same labeling system will be used.

3. Conditions of Use:

   3.1 Confirm that the C-337A source will only be used in the Model 880 Delta. If the source will be used in the Model 880 Sigma and Elite, please specify that the maximum activity in the Sigma and Elite models will be in conformance with the values listed in the device registration.

   3.2 Provide information on whether the MDS Nordion male connector will still be used in conjunction with the C-337A source assembly in the Model 880. The conclusion regarding the male connector is stated on page 9 of 12, of the MDS Nordion application registration of the C-337A Ir-192 sealed source, dated November 13, 1997.

   3.3 Provide the expected working life of the source.

4. Prototype Testing:

   Provide information that the Model C-337A source, when installed in the Model 880 series exposure devices, will maintain its integrity when subjected to normal use and likely accident conditions. In providing this information, you may use any of the methods listed in Section 10.5, Prototype Testing, NUREG-1556, Vol. 3; i.e., actual history of the product, engineering analysis, operational history, or comparison to similar or equivalent models.

5. Radiation Profiles:

In accordance with Section 10.6, NUREG-1556, Vol. 3; provide the radiation levels around the Model 880 series exposure devices with a Model C-337A source of maximum activity. Please note that Registration Certificate No. MA-1059-D-334-S specifies different maximum source activity for the various models in the series.

September 9, 2003

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

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION ON AMENDMENT FOR RADIOGRAPHIC SOURCE ASSEMBLY (NR-0220-S-112-S)

Dear Mr. Charette

This letter is in response to your application dated June 13, 2003, for an amendment to the sealed source registration NR-0220-S-112-S for the Model C-337A radiographic source assembly. In reviewing your application, we find that it is lacking required information. In the Enclosure of this letter, we have summarized the issues not addressed in your application.

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.

Please also note that upon approval of your request you should ask the Radiation Control Program, Department of Public Health, State of Massachusetts, who issued the Registration Certificate No. MA-1059-D-334-S, to add the Model C-337A source for use in the Model 880 Series radiography exposure devices.

If you have any questions, please contact me at (301) 415-7138 or Dr. John P. Jankovich at 301-415-7904.

Sincerely,
/***RA***/
Tomas Herrera, Nuclear Safety Intern
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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