

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

November 9, 2001

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

Dear Mr. Charette:

Based on the information in your application dated April 19, 2001, and subsequent correspondence, we conclude that the GammaMed Model 212 Medical Brachytherapy Source Assembly is acceptable for licensing purposes in accordance with the conditions of the enclosed registration certificate (NR-0220-S-124-S).

Please be advised that you must manufacture and distribute the product in accordance with the statements and representations contained in your application and subsequent correspondence, with enclosures thereto, and the information set out in your registration certificate. As a general rule, you must request and obtain an amendment to the certificate before you make changes or modifications to the information submitted to obtain the certificate.

Please read over the registration certificate in its entirety and notify us immediately of any errors or omissions. You are obligated to notify us promptly in writing should you decide to no longer manufacture or offer service support for the product.

Please be aware that, as a holder of an NRC registration, you may be subject to the NRC's licensing and inspection fees in accordance with 10 CFR Part 170, and annual fees in accordance with 10 CFR Part 171. If you have any questions concerning the fee requirements, please contact the License Fee and Accounts Receivable Branch at (301) 415-7554.

If you have any questions, please contact me at (301) 415-7038 or Dr. Seung Lee at (301) 415-5787.

Sincerely.

William R. Ward, Mechanical Engineer Materials Safety & Inspection Branch

Division of Industrial and **Medical Nuclear Safety**

Office of Nuclear Material Safety

and Safeguards

Enclosure: As stated

cc w/encl: RJones, LFARB

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Sincerely,

/RA/

William R. Ward, Mechanical Engineer Materials Safety & Inspection Branch Division of Industrial and Medical Nuclear Safety Office of Nuclear Material Safety and Safeguards

Enclosure: As stated cc w/encl: RJones, LFARB

Distribution:

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NR-0220-S-124-S

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