

April 24, 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 and test data submitted with your request dated October 11, 2000, and subsequent correspondence, with enclosures thereto, we conclude that the GammaMed Models 12i, 12it and Plus afterloading brachytherapy devices and the GammaMed Plus source Model 232, are acceptable for licensing purposes in accordance with the conditions of the enclosed registration certificates (NR-0220-D-121-S, NR-0220-D-122-S and NR-0220-S-123-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 Mr. Seung Lee at (301) 415-5787.

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

Enclosures: As stated
cc w/encl: SKimberley, LFARB

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SSD-00-44

SSD File # NR-0220-D-122-S

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