

December 10, 2001

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

Dear Mr. Charette:

As you requested in your letter dated June 18, 2001, we have amended registration certificate number NR-0220-S-123-S, for the GammaMed 232 source, based on information submitted in your letter. A copy of the amended registration certificate will be provided under separate correspondence.

During our review of your amendment request, we realized we had previously overlooked the requirements of 10 CFR 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use", as they apply to the GammaMed 232 source and the GammaMed Plus device (NR-0220-D-122-S). A similar situation was noted with the GammaMed 212 source and GammaMed 12i/12it devices. That situation was resolved by the addition of a new label to the GammaMed 12i/12it devices.

We are requesting that you contact us concerning amending the GammaMed Plus device registration certificate to include a new label, similar to the one added to the GammaMed 12i/12it devices, to meet the requirements of 10 CFR 32.74. You should also provide information on the process and timing of how the addition of the new labels will be accomplished.

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

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

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SSD 01-32 NR-0220-D-122-S NR-0220-S-123-S ADAMS ML013390508

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