447 March Road Ottawa, Ontario Canada K2K 1X8 Tel: 613 592-2790



Science Advancing Health

December 14, 2001

Dr. John J. Jankovich
Seal Source and Device Team Leader
Mail Stop: T-8F5
United States Nuclear Regulatory Commission
Two White Flint North
11545 Rockville Pike
Rockville, MD
20852-2738

Dear Dr. Jankovich:

### **RE:** Name Change on Device Registrations

I am writing to you, to request an amendment to the Registry of Radioactive Sealed Source and Devices Safety Evaluation of Sealed Source for all the sources and devices listed in Annex 1. This amendment is required to change the name and address of MDS Nordion as listed below. Please note that the quality assurance and quality control programs will remain the same. The technical staff administrating these programs has not changed. This request is solely a name and address change and does not represent a change in design, labelling or operating procedures. The quality assurance program has not been changed.

1) The name of our corporation was changed from MDS Nordion Inc. to MDS (Canada) Inc. on November 1<sup>st</sup>, 2001. The name change is the result of a statutory amalgamation. MDS Nordion is now a division of MDS (Canada) Inc. MDS Nordion without the "Inc." will continue to be the name under which MDS (Canada) Inc. carries on business. It is for this reason that we would like to request that our corporate name found on the Registry of Radioactive Sealed Source and Devices Safety Evaluation of Sealed Source listed in Annex 1 be changed to "MDS Nordion, a Division of MDS (Canada) Inc." This is strictly a name change exercise. The ownership, management and operation of our company remain unchanged and the same. Please refer to the enclosed letter from our Legal Counsel, Re: MDS Nordion Inc. – Notice of Change of Corporation Name.

Our address has changed from Kanata to Ottawa. The city of Kanata was amalgamated along with a dozen other municipalities into the city of Ottawa on January 1st 2001. The reminder of our address and other co-ordinates remain unchanged. We would appreciate if our address could be changed from the municipality of Kanata to the municipality of Ottawa on the Registry of Radioactive Sealed Source and Devices Safety Evaluation of Sealed Source listed in Annex 1. Please refer to the enclosed letter from our Legal Counsel, Re: Change in Mailing Address.

Hence the new name and address for the Distributor and Manufacturer (when required)

MDS Nordion.

A division of MDS (Canada) Inc.

447 March Road Ottawa, Ontario

Canada, K2K 1X8

If you have any questions or require further information please feel free to contact me by telephone at (613) 592-3400 extension 2421 or by email at mcharette@mds.nordion.com.

Yours sincerely

Marc-André Charette

Regulatory Affairs Senior Associate

MDS Nordion

Enclosed: MDS Nordion Inc. – Notice of Change of Corporation Name, Change in

Mailing Address

# Annexe 1

Item	Device/Source	Registration
1	Gammacell 40 (Serial No. 1 thru 133)	NR-0220-D-101-S
	Gammacell 40 Exactor (Serial No. 134 & higher)	
2	Gammacell 1000, 1000 Elite, 3000 Elan	NR-0220-D-102-S
3	C-188 (series) Types 1–13, C-306 (series) Types 1-2	NR-0220-S-103-S
4	Gammabeam 150 A, B and C	NR-0220-D-105-S
5	C-265	NR-0220-S-106-S
6	Gammacell 220	NR-0220-D-107-S
7	C-349	NR-0220-S-108-S
8	C-337	NR-0220-S-111-S
9	C-337A	NR-0220-S-112-S
10	TheraSphere	NR-0220-D-113-S
11	T1000, T1000E and Elite 100	NR-0220-D-114-S
12	C-151/C-152	NR-0220-S-115-S
13	C-146/C-196	NR-0220-S-116-S
14	Theratron 780 Series (780, 780C, T780E, Phoenix,	NR-0220-D-117-S
	Elite 80)	
15	Theratron 780-19	NR-0220-D-118-S
16	XC-325	NR-0220-S-119-S
17	C-198	NR-0220-S-120-S
18	GammaMed 12it, GammaMed 12i	NR-0220-D-121-S
19	GammaMed Plus	NR-0220-D-122-S
20	GammaMed 232	NR-0220-S-123-S
21	GammaMed 212	NR-0220-S-124-S



November 1, 2001

To whom it may concern:

# Re: MDS Nordion Inc. - Notice of Change of Corporation Name

Please be advised that, as a result of a statutory amalgamation, MDS Nordion Inc. and MDS Pharma Services Inc. have amalgamated to become MDS (Canada) Inc., effective November 1, 2001.

MDS Nordion is now a division of MDS (Canada) Inc., and MDS Nordion will be a name or style under which MDS (Canada) Inc. carries on business.

Yours very truly,

Aichael 1

Richard Stacey Legal Counsel

#48799



November 21, 2001

#### TO WHOM IT MAY CONCERN:

## Re: Change in Mailing Address

Please be advised that our address for mailing purposes has changed from the City of Kanata to the City of Ottawa. Please note, however, that Kanata and Ottawa will continue to be considered as one and the same for postal services purposes.

Yours very truly,

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Richard Stacey Legal Counsel