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July 12, 2000

Mr. Frederick Sturz  
Section Chief  
Mail Stop: 6F18  
United States Nuclear Regulatory Commission  
One White Flint North  
11555 Rockville Pike  
Rockville, MD  
20852-2738

Dear Mr. Sturz:

**RE: Name Change and Amendment to the Device Registration  
NR-687-D-105-S & NR-687-D-101-S**

Thank you for your letter of June 15, 2000, regarding the Theratronics name change and amendment to the device registration. I have reviewed the registration certificate and found one item, which may require further clarification. The registration certificates for both the T1000 (NR-220-D-114-S) and Theratron 780 series (NR-220-D-117-S) include the operating features of the Computerized Console Upgrade. As this is an upgrade some customers may choose to purchase it and others may not. Currently the wording in the registration certificate seems to indicate that all the T1000 and Theratron 780C units include the computerized console, which is not the case. Please consider incorporating the proposed wording below:

For the T1000 registration certificate NR-220-D-114-S, page 4:

“The Model Elite 100, the Model T1000E, and the upgraded console Model T1000, when equipped with a retrofit kit, marketed by the manufacturer as an option for the user, meet the provisions of the International Electrotechnical Commission Standard IEC 601-2-11, Second Edition 1997. In addition, the model Elite 100 also includes the design features of the Model T1000E.”

For the Theratron 780 registration certificate NR-220-D-117-S, page 5:

“The Model Elite 80, the Model T780E, and the upgraded console the Model 780C, when equipped with a retrofit kit, marketed by the manufacturer as an option for the user, meet the provisions of the International Electrotechnical Commission Standard IEC 601-2-11, Second Edition 1997-08, including Amendments #1-1992, and #2-1995. In addition, the model Elite 80 also includes the design features of the Model T780E.”

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](mailto:mcharette@mds.nordion.com).

Yours sincerely

A handwritten signature in black ink, reading "Marc-André Charette". The signature is fluid and cursive, with a long horizontal stroke extending from the end.

Marc-André Charette  
Regulatory Affairs Senior Associate  
MDS Nordion