

NOTE TO FILE

August 5, 2001

SSD Case number 00-33

SSD Certificates **NR-0220-D-114-S**, dated January 12, 2001
and **NR-0220-D-117-S**, dated January 12, 2001
for the Theratron T1000 and 780 series Teletherapy Units

MDS Nordion

Why no checklist was used for either certificate in SSD case # 00-33

No checklist was used because this amendment request was administrative in nature. These devices had recently been reviewed (certificates issued in June 2000). In reviewing the certificates, Nordion noted that the wording seemed to indicate an option on the units was a standard feature. Nordion requested an amendment to correct the wording to clearly indicate the option as an option. No technical review was performed on this amendment request.

Why there is no working life specified in certificate NR-0220-D-117-S

This certificate was transferred from Theratronics to Nordion in June 2000. Since this action was primarily to change the name and no technical review was performed, no working life was added into the certificate. When the Nordion certificate was amended for administrative reasons in January 2001, again no technical review was performed and no working life added. A working life should be added the next time this certificate is technically reviewed.

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ADAMS accession number **ML012170001**