

Mr. David Duersteler
Safety & Regulatory Engineering
GE Medical Systems
300 North Grand View Blvd.
Waukesha, WI 53188
USA

Date: July 18, 2000

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR MODEL V-TransACT
SSD 00-03

Dear Mr. Durersteler:

We have reviewed your application dated January 18, 2000, requesting Sealed Sources and Devices Evaluation and registration of Model V-TransACT Rod Unit. In reviewing the application information, we find the application is lacking significant amounts of information for us to reach a decision. Therefore, we request that you address the issues outlined in the attached Enclosure.

Please respond within 30 days of the date of this letter and be certain to address all the areas of concern cited herein. If you would like to discuss any of the issues identified in this letter or have any questions, please contact me at (301) 415-7894.

Sincerely,

/RA/

Ujagar S. Bhachu, PEng. CEng., Mechanical Engineer
Materials Safety and Inspection Branch,
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards.

Enclosure: As stated
cc. w/encl: S. Kimberly, LFARB

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