

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

September 18, 2000

Subject: DISCONTINUATION OF SEALED SOURCE AND DEVICE REVIEW FOR
REGISTRATION OF GENERAL ELECTRIC MEDICAL SYSTEMS MODEL
V-TransACT ROD UNIT. SSD 00-03.

Dear MR. Duersteler:

This letter is in reference to GE Medical Systems' application dated January 18, 2000, requesting Sealed Source and Device evaluation and registration of Model V-TransAct Rod Unit. On September 7, 2000, GE Medical Systems requested by E-Mail additional 30 days to respond to the NRC'S request for addition information dated July 18, 2000.

During August and September Mr. Bhachu of my staff called you and Dr. James Beebe of GE Medical Systems as reminders that the requested information is pending. We still do not have adequate information to complete the review and registration of this device. Because you failed to respond to our request for additional information within 30 days from the date of request, we are discontinuing our review of your application. This is without prejudice to the submission of the requested information. At such time, we will resume our review and evaluation of your device as a new application.

If you have any questions, please contact me at (301) 415-7273 or Ujagar S. Bhachu on (301) 415-7894.

Sincerely,

/RA/

Frederick Sturz, Section Chief
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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cc. SKimberley, LFDCB

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