June 30, 1999

Mr. James E. Beebe, Ph. D.
X-Ray Projects - Safety & Regulatory Program MANAGER
General Electric Medical System
P.O. Box 1414, W-641
Milwaukee, WI 53201-0414

Dear Dr. Beebe:

We have reviewed your response dated February 2, 1999, to our letter dated January 19, 1999, outlining the deficient items in your application, related to the V-Transact Rod Unit Attenuation System. We find your information submitted to date lacking significant amounts of the required information for us to reach a decision. With incomplete documents and inadequate information we are not able to complete our evaluation of your device. Therefore, we have discontinued our review of your application.

Our discontinuance of the review is without prejudice to re-submission of your application. If you decide to re-submit your application for registration, please ensure that you have included sufficient information to allow NRC to evaluate your device in a timely manner. Enclosure 1, is a summary of our major areas of concern that you need to address. Enclosure 2, a copy of NUREG 1556 Vol. 3 which should help you in preparing a complete application.

Please be advised that issues related to your request for withholding of information will be addressed and transmitted to you separately.

If you have any questions, please call me on (301)415-7231 or Ujagar S. Bhachu of my staff at (301)415-7894.

Sincerely,

/s/

Larry W. Camper, Branch Chief
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosures: As stated
cc. w/encl: Skimberly, LFDCB

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Enclosure 1

ELGEMS V-TransACT

1.0 GENERAL

1.1 Please specify the type of license under which the V-TransAct will be used. NUREG 1556 Vol. 3, Section 10 requires that the applicant identify whether the device is intended to be used under a specific license, general license, or both.

2.0 SOURCE REGISTRATION CERTIFICATE (MA-0476-S-117-S)

2.1 Please provide a copy of the appropriate Federal Food and Drug Administration. (FDA) approval. As indicated in NUREG 1556 Vol. 3, Section 5.7, it is a NRC policy to preclude the approval of a medical source or device unless the applicant has submitted a copy of the pre-marketing approval of Form 510(k) by the FDA.

2.2 Please clarify inconsistencies in your application and the source registration certificate referenced in your application. The drawing attached to the registration certificate, dated 06/11/98, excludes model NES-8429. For this model a maximum activity of 600 millicuries (22.2 Gbq) is indicated on page 2 of the registration certificate. However, registration certificate Attachment 1, Note 1 provides tolerances for nominal activities. A copy of source purchase order included in Appedix 'C' Prototype Testing indicates sources activity as 450 millicurie (16.56 Gbq.) In a Dupont memo issued on January 28, 1999 the maximum activity of the line source is 540 millicuries for a 20" active length. Please explain the existence of these differing activity values for the source. (Please be advised that the referenced registration certificate was revised and reissued on April 01, 1999.)

2.3 Please state how the two source "L" deployment and TC-99m transmission effects on the bonding capability of the epoxy were taken into consideration and how the working life of the source was established. The bonding capability of the epoxy was evaluated using a single source.

2.4 Please justify the transposition and linear extrapolation of the data from Fe-55 to Gd-153 based on energy absorption. Please explain how the two isotopes' energy spectra and intensity of the emitted photons were accounted for in assessing the working life of the source.

2.5 Please clarify inconsistencies in manufacturing tolerances. The registration certificate provides differing manufacturing tolerances. Please state which dimensional tolerances will apply to your model the ones indicated in the Attachment 1, Note 8, the Model Number Table or the one's indicated in the sketch title block.

2.6 Please state the maximum activity that could be put into the device. This should include nominal value with tolerance form. (See NUREG 1556 Vol. 3 Section 10.1 page 10-2 and Section 12.2, page 12-1.) It is the responsibility of the manufacturer that the activity shipped is within the maximum stated on the certificate. If the manufacture cannot ensure that the maximum activity is not to exceed due to loading tolerances, they must describe this in the SS&D application and the regulatory body will review it during the approval process.

2.7 Provide the radiation exposure for workers and other personnel when the patient is under going emission and transmission and confirm that 10 CFR Part 20 occupational and public dose limits will not be exceeded. (See Section 10.6 of the NUREG 1556 Vol. 3.)

3.0 TEST REPORT- APPENDIX "C"

3.1 Please submit a copy of MIL-STD-810D, Method 514.2 Procedure 1 (See page G-9.) It appears that this is an incorrect reference.

The device operational cyclic test should include the shutter mechanism as well as the mechanical drive, and the shielding mechanism functions of the device. Full consideration should be given to accident conditions during transportation, normal and abnormal operations. Please note three hour test durations are inadequate. What is the longest shipment distance in miles? Please state the basis of vibration spectra, test duration's selection criteria for each axis and type of transportation carrier assumed. A device cyclic test of 2500 cycles per year for shutters is inadequate for a device life of 10 years. Please explain this apparent discrepancy.

3.3 Please provide reliability history of usage of the solenoid, shutter arrangements and associated ball bearings.

4.0 OPERATIONAL MANUAL

4.1 Please clarify inconsistencies in the operational manual. The manual has been revised and it is difficult to tell which pages have been changed. Chapter 6.0 has been added. The tables of contents of the manual show one page, however, Chapter 6 actually has two pages.

4.2 The operational manual (pages 1-3 and 1-8) states that the rod units , removal replacement, installation and repair of the rod units must be performed only by qualified service personal authorized by the vendor. Please state the minimum qualification requirements for these activities.

5.0 SERVICE MANUAL

Please provide a complete service manual. The service manual needs to address the following items:

5.1 Page 1-7. Please confirm that the use of IEC symbols will not confuse or mislead the operators in USA.

5.2 Page 1-8. Please revise the manual as necessary. The reference to regulatory requirements in manual is misleading. National standards are not considered regulatory requirements in the USA as these are written and enforced by independent bodies. However, industrial standards can be made part of the regulatory requirements by reference.

6.0 QUALITY ASSURANCE

6.1 You have not submitted Appendix H I and J as part of Package 1. We need the previously submitted information in your application to complete our review.

6.2 Please provide a copy of your ISO 9001 certification.

6.3 Please state who is responsible for the quality assurance for the loading and unloading of devices and sources. Also state the measures to be taken to assure conformance with specifications of the device radiation profiles by measuring primary emissions and pre- and post-installation background radiation levels.

7.0 REGULATORY REQUIREMENTS

7.1 Please confirm that your application satisfies the regulatory requirement of 10 CFR 32.74 and requirements of 10 CFR 20, Subpart J. (See Section 10.4 of NUREG 1556 Vol. 3.)

7.2 Please provide occupational exposure during loading and unloading of sources, and leak testing to be performed by the distributor's qualified service personnel.