UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

DATE: 5/9/88

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY

FAX TRANSMITTAL

TO	LOCATION
1. Dr. James Beebe	
FAX # (414) 544-3863	VERIFICATION ( )
2.	
FAX # ( )	VERIFICATION ( )
3.	
FAX # ( )	VERIFICATION ( )
4.	
FAX # ( )	VERIFICATION ( )

COMMENTS:
Please respond in 30 days.

COVER SHEET PLUS 3 PAGES

FROM: Seung Lee

PHONE: (301) 415-5787
FAX: (301) 415-5369

We are in the process of reviewing your application. However, in order to continue our review, we need the following information:

1. NRC policy precludes the approval of a medical sealed source or device unless the applicant has submitted a copy of the pre-marketing approval [510(k)] issued by FDA. Because the pre-marketing approval is not submitted with the application, you should contact the FDA and obtain the appropriate approval. You may contact Food and Drug Administration, Office of Compliance, HFZ-300, 2098 Gaither Road, Rockville, MD 20850, (301) 594-4692.

2. Provide the absolute value for maximum activity that could be put into the device, not a nominal value with ± tolerance form. The manufacturer must ensure that the activity shipped is within the maximum listed on the certificate. If manufacturers cannot ensure that the maximum activity is not exceeded due to loading tolerances, they must describe this in the SS&D application and NRC will review it during the approval process.

3. Using your assumption, we estimated that there will be more 25,000 shutter operations during the 10 year life time of the device. Provide the basis for concluding that the device is expected to operate safely for 10 years. Your original justification is based on the 1 year simulated shutter testing (2,500 operations).

4. Provide additional information regarding the rotational spring solenoid: (1) how is it prevented from being stuck open in case of power failure, (2) the means for the backup power, (3) the information on the solenoid such as manufacturer, reliability, history of usage, and (4) report 475-3685-0002 on page G-4.

5. The application includes engineering drawings that are marked as proprietary. Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.790. You must list all portions that you wish to be held proprietary, along with your reasons as to why the information is proprietary. Please keep proprietary information to a minimum.

6. Provide engineering drawings for the rod bolt, shutter locking lever, and locking screw.

7. Provide the information on the temperature buildups on both ends and middle of the source and its affect on the degradation of the epoxy used for source adhesive.

   Provide the information on how the rod source holder house holds the active source. Based on the drawing no. 119040005, there is void space of 2.5 mm in the rod source lead finish with 20.3" overall length.

   Provide the height, thickness of all side walls in the rod source house in the drawing no. 119040005.

   Provide a copy of MIL-C-13924 Class 1 standard.

8. Revise the Label 1 in accordance with 10 CFR 32.74 (a)(3) by inserting the following or similar statement: "The U.S. NRC has approved distribution of the (name of source or

device) to persons licensed to use byproduct material identified in 35.57, 35.400, or 35.500, as appropriate, and to persons who hold an equivalent license issued by an Agreement State."

9. 10 CFR 32.74(a)(2)(viii) requires that, if the instructions for handling and storing are too lengthy for the label, the instructions should be summarized on the label and printed in detail in a brochure which is referenced on the label. Therefore, please revise the source label or device label in accordance with 10 CFR 32.74(a)(2)(viii).

10. Provide the maximum installation height for this device in order to validate the drop test.

11. Explain how the radiation readings are extrapolated from those taken with a 297 mCi to ones with a 450 mCi activity.

12. Provide (1) a copy of current ISO 9001 certificate for Elgems, and (2) GE's QA/QC program as applied to receipt inspection, installation, and use in the USA.

13. In the Service Manual, (1) complete the sentence for the 1 Rad in the second paragraph on page 1-5, (2) correct 5ηCi to 5 nCi or 0.005 mCi (185 Bq) on page 3-7 (also in the fourth step of the Radiation Leakage Test on page 4-5 of the Operational Manual), (3) provide missing page 4-5, (4) clarify the first step in Section 5.1.1., "Disassembling the Rod Units," and (5) change warning statement on page 5-4 from "State agreement" to "an Agreement State."

14. Provide the NER-462 Fe-55 source evaluation report as cited on page D-3.

15. Provide the test results of 1 hour of vibration in three axes simultaneously for transportation, page G-8.

16. Provide any special procedures for installation of the components such as mounting, interlocks, guards or barriers at the user's facility.

Please provide the requested information within thirty (30) days. If we do not receive the requested information within thirty (30) days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application. If you have any questions, please contact me at (301) 415-5787.