ELGEMS **P.O.Box 170 – Tirat Hacarmel 30200 ISRAEL**
Tel 972-4-8563666 – Fax 972-4-8577663

1/6/99

Dear reviewer Mr. Seung Lee,

According to your letter (e-Mail) to Mr. Beebe dated on May 6,1999, we send you the attached file with the required information to continue the review and evaluation of MG ATC system.

The answers and explanations were inserted into your letter (**bold letters**) after each required clarification.

The following appendices were include

Appendix A – update MG ATC Operation Manual
Appendix B – updated MG ATC Service Manual
Appendix C – Test Reports
Appendix D - Engineering Drawings & Data Sheets
Appendix E - Copy of MIL-C-13924 Class standard
Appendix F - Copy of current ISO 9001 certificate for Elgems
Appendix G – NER-462 Source Window Safety Evaluation

We would like to thank you for your cooperation, answering our questions and clarifying the requested data , hoping that now, this corrected and updated submission will fulfill the completion of the review and evaluation of the device.

Sergio Steinfeld
MG ATC System Engineer
R&D Dept.
Tel 972-4-8563642
Fax 972-4-8577662
E-Mail : sergio_steinfeld@elgems.com

NRC FORM 567
(8-93)

U. S. NUCLEAR REGULATORY COMMISSION

REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

INSTRUCTIONS: Send this request AND a copy of all related letters/applications and drawings to: The Sealed Source Safety Section, ATTN: Chief, OWFN Mail Stop 6 H3. Change the License Tracking System milestone to 19 and assign to reviewer code I-5.
NOTE: Retain a copy of this request with the application and background files.

REQUESTER: GE Medical Systems	REGION/LOCATION: ☐ I ☐ II ☐ III ☐ IV ☐ V ☐ HQ ☐ LFDCB
TELEPHONE NUMBER: 414-544-3061 / DATE:	TYPE OF ACTION REQUESTED (Check as appropriate)
APPLICANT'S NAME: JAMES E. BEEBE	☐ SOURCE REVIEW ☐ DEVICE REVIEW ☐ CUSTOM REVIEW ☐ AMENDMENT OF REGISTRATION SHEET NUMBER(S)
MAIL CONTROL NUMBER(S): APRIL 2, 1999	
LETTER/APPLICATION DATE / LICENSE NUMBER(S)	

COMMENTS:
P.O. BOX 414, W-709
MILWAUKEE, WI 53201-0414

FOR SSSS USE ONLY

REVIEWER	MODEL NUMBERS	NUMBER ASSIGNED
SEUNG LEE	ATC Rod Unit	99-23
DATE RECEIVED	**DATE ASSIGNED**	**DATE TO FEES**
4-5-99	4-5-99	4-5-99

TYPE OF ACTION (Indicate the number of each type)

☒ COMMERCIAL DISTRIBUTION (FORMAL) ☐ USE BY A SINGLE APPLICANT (CUSTOM)

SOURCE (9C)	DEVICE (9A)	SOURCE (9D)	DEVICE (9B)
☐ NEW ☐ AMENDMENT	☒ NEW ☐ AMENDMENT	☐ NEW ☐ AMENDMENT	☐ NEW ☐ AMENDMENT

☐ NO SAFETY EVALUATION REQUIRED
NO FEES REQUIRED

☐ LICENSING ACTION REQUIRED IF KNOWN ☐ YES ☐ NO

☐ OTHER *(Specify)*

	TOTAL NUMBER OF REVIEW HOURS
	NUMBER OF DEFICIENCY LETTERS
	NUMBER OF DEFICIENCY CALLS

NOTES: Application for REGISTRATION OF THE Attenuation Correction OPTION for use in Gems dual HEAD Nuclear Med. Imaging Sys

FOR BILLING PURPOSES ONLY

☐ NAME CHANGE ☐ ADDRESS CHANGE ☐ NEW REGISTRATION -- ADD TO BILLING ☐ PRODUCT INACTIVE -- REMOVE FROM BILLING

FOR FEE USE ONLY

TYPE OF FEE: APP	FEE CATEGORY: ☒ 9A ☐ 9B ☐ 9C ☐ 9D	
AMOUNT RECEIVED: # 360 00	CHECK NUMBER: 0014244168	☐ MATANN UPDATED AS REQUIRED
DATE OF CHECK: 4/21/99	LOG: Apr 1995+D	☐ MATSYS UPDATED AS REQUIRED
APPROVED BY: [signature]	DATE RETURN: 4/29/99	DATE
COMMENTS		

NRC FORM 567 (8-93)

ORIGINAL TO SSSS

NRC FORM 567
(8-93)

U. S. NUCLEAR REGULATORY COMMISSION

REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

INSTRUCTIONS: Send this request AND a copy of all related letters/applications and drawings to: The Sealed Source Safety Section, ATTN: Chief, OWFN Mail Stop 6 H3. Change the License Tracking System milestone to 19 and assign to reviewer code I-5.
NOTE: Retain a copy of this request with the application and background files.

REQUESTER: GE Medical Systems	REGION/LOCATION: ☐ I ☐ II ☐ III ☐ IV ☐ V ☐ HQ ☐ LFDCB
TELEPHONE NUMBER: 414-544-3061	DATE:
APPLICANT'S NAME: James E. Beebe	TYPE OF ACTION REQUESTED (Check as appropriate)
MAIL CONTROL NUMBER(S): April 2, 1999	☐ SOURCE REVIEW ☐ DEVICE REVIEW ☐ CUSTOM REVIEW ☐ AMENDMENT OF REGISTRATION SHEET NUMBER(S): N/A
LETTER/APPLICATION DATE	LICENSE NUMBER(S)

COMMENTS:
P.O. Box 414, W-709
Milwaukee, WI 53201-0414

FOR SSSS USE ONLY

REVIEWER	MODEL NUMBERS	NUMBER ASSIGNED
Seung Lee	ATC Rod Unit	99-23
DATE RECEIVED	**DATE ASSIGNED**	**DATE TO FEES**
4-5-99	4-5-99	4-5-99

TYPE OF ACTION (Indicate the number of each type)

☒ COMMERCIAL DISTRIBUTION (FORMAL) ☐ USE BY A SINGLE APPLICANT (CUSTOM)

SOURCE (9C)	DEVICE (9A)	SOURCE (9D)	DEVICE (9B)
☐ NEW ☐ AMENDMENT	☒ NEW ☐ AMENDMENT	☐ NEW ☐ AMENDMENT	☐ NEW ☐ AMENDMENT

☐ NO SAFETY EVALUATION REQUIRED NO FEES REQUIRED ☐ LICENSING ACTION REQUIRED IF KNOWN ☐ YES ☐ NO

☐ OTHER *(Specify)*

	TOTAL NUMBER OF REVIEW HOURS
	NUMBER OF DEFICIENCY LETTERS
	NUMBER OF DEFICIENCY CALLS

NOTES: Application for REGISTRATION OF THE Attenuation Correction OPTION for use in Gems dual HEAD Nuclear Med. Imaging Sys.

FOR BILLING PURPOSES ONLY

☐ NAME CHANGE ☐ ADDRESS CHANGE ☐ NEW REGISTRATION – ADD TO BILLING ☐ PRODUCT INACTIVE – REMOVE FROM BILLING

FOR FEE USE ONLY

TYPE OF FEE: APP	FEE CATEGORY: ☒ 9A ☐ 9B ☐ 9C ☐ 9D	
AMOUNT RECEIVED: # 3600	CHECK NUMBER: 0014244168	☐ MATANN UPDATED AS REQUIRED
DATE OF CHECK: 4/21/99	LOG: Apr 1999 SS+D	☐ MATSYS UPDATED AS REQUIRED
APPROVED BY:	DATE RETURN: 4/29/99	DATE:
COMMENTS:		

NRC FORM 567 (8-93)

ORIGINATORS COPY

NRC FORM 577 (5-1998) U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

ATTN: Sandra Kimberley, MS T-9E10
U.S. Nuclear Regulatory Commission
License Fee and Accounts Receivable Branch
P. O. Box 954514
St. Louis, MO 63195-4514

GE Medical Systems
ATTN: James E. Beebe, Ph.D.
Safety & Regulatory for X-Ray,
Nuclear Medicine & PET
P.O. Box 414, W-709
Milwaukee, WI 53201-0414

TYPE OF ACTION

- [x] NEW LICENSE
- [ ] RENEWAL OF LICENSE
- [ ] AMENDMENT TO LICENSE

REQUESTED DATE: 04/01/1999

LICENSE NUMBER: New

CONTROL NUMBER: 99-23

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of 10 CFR Part 170. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
9A	$ 3,600.00	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE	$ 3,600.00
PAYMENT RECEIVED	$ 0.00
AMOUNT DUE	$ 3,600.00

- [x] Your request was received without the prescribed application fee.
- [ ] We received your check listed below. Payment of the additional fee noted above is required.
  - _____ Check Number
  - $ 0.00 Amount
- [ ] Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).
- [ ] Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

- [ ] _____ Check Number — Enclosed is your check which accompanied your request. The fee is not required because:
- [ ] _____ Check Number — We received your check listed in payment of the fee.
- [ ] _____ Date of Request; _____ Control Number — The Licensing staff has informed us that your request is to be considered as a continuation of the request listed.
- [ ] _____ Date of Request; _____ Control Number — Your request was combined, prior to review, with the request listed.

III. CHECK RETURNED

- [ ] _____ Check Number — Enclosed is your check which was returned to us by the bank for:
  - [ ] INSUFFICIENT FUNDS
  - [ ] ACCOUNT CLOSED
  - [ ] OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

- [ ] _____ License Number; _____ Amendment Number; _____ Date Issued — The listed license was issued without the required fee being collected. The fee required is noted in Section I of this form.
- [ ] The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).
- [ ] Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE -- LICENSE FEE ANALYST	LFDCB	LFDCB	Distribution:	DATE
Sandra Kimberley, 301-415-6096	sk 4/8/99		OC/DAF/LFARB S/F (LF-3.2.7) OC/DAF/LFARB RF OC/DAF R/F; Pending Cy; cc: TKime	04/08/1999

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.

The MG ATC pre-marketing application file (510k) was sent to FDA on the 1/6/99. After receiving 510(k) number from the FDA, we will inform you immediately. Please, continue the review and evaluation of the device.

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.

We've requested the source supplier information and received the following answer :

"The maximum activity loading for the NES8429 Gd-153 Line Source is 540 mCi. All sources are loaded to a nominal 450 mCi, having an upper tolerance of +20% and lower tolerance of -10%.

Ron Brown (from DuPont Laboratories) "

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).

The electromechanical design of the shutter mechanism is based on both static and dynamic components. The life expectancy of the device is 10 years. During those 10 years, the shutter mechanism completes about 1 million open/close cycles.

The static elements have been designed and analyzed according to IEC-601-1. The static strength safety factor of these elements is > 8 for elements subjected to fatigue, corrosion and wear, all other static elements has safety factor > 4.

There are two dynamic components in the device : the solenoid and the ball bearing. The solenoid chosen (see attached in appendix D data sheet, RE Type-Extended life : 10 million cycles) will provide a life expectancy of more that 10 years since the operation conditions complies with the manufacturer recommendations. The ball bearing chosen (see attached in appendix D data sheet, SKF 618/6 , including isometric draw No. 4 indicating its position at the front-end of the rod assembly) will provide life expectancy of more that 10 years since the maximum radial and axial loads are 2.5N.

The mentioned principles provide the basis for concluding that the device is expected to operate safely for 10 years.

The shutter was tested for 100,000 operations , the equivalent for one year of use and no failures were observed (see on appendix C, test report MG ATC Rod Shutter – Radiation Safety & Reliability).
Note: The value of 2,500/year shutter operations presented in the original submission was not corrected.

Furthermore, the device has a few safety guards and quality procedures to assure properly functionality of the system :

a) **Two slotted opto-couplers switches which sense both positions of the tungsten rod shutter (close and open) are on line monitoring by the system, also when the MG ATC option is not activated, in order to assure the normally shutter close position. In case of any malfunction, the system displays, in the acquisition station, an error message " Source Is Open – Close Safety Handle". Safety instructions are described in the MG ATC Operation Manual.**
See reference in appendix A, MG ATC Operation Manual page 3-7, Safety Precautions
b) **A yellow Led indicates the when the shutter is open, no matter if power is supplied to the solenoid or not. The led is activated according to the position of the slotted opto-coupler switch which sense the position of the tungsten rod shutter. The led inspection is done every six month by the service engineer.**
See reference appendix A, MG ATC Operation Manual pages 1-5 and 2-7.
See reference appendix B, MG ATC Service Manual , page 5-6.
See reference, for the slotted opto-couplers switches assembly, drawing OPT000052 page 4 on appendix I of the original submission file (I-13).
c) **The shutter test, performed every power _on of the system, performs a three stages cycle (closing, opening, closing) of the shutter mechanism checking the right status of the slotted opto-couplers switches. In case of failure, an error message is displayed in the acquisition station.**
d) **<u>Radiation Leakage Tests</u> : the camera should be checked for radiation leaks at least once every six month or earlier is stipulated by local safety regulations. Two test should be performed by the user : Dry Wipe Test and the Leakage Measurement**

Test . Description of the tests can be found in appendix A, MG ATC Operation Manual , chapter 4 Maintenance, page 4-5.

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.

(1) The solenoid shutter mechanism is a normally closed.
The shutter is opened under electrical power and is closed by spring.
The shutter mechanism is inside closed case to prevent dirt and obstacles from interfering the smooth movement of the shutter.
The spring moment is calculated and tested to overcome friction and mass moments:
Return spring torque is 0.0165-0.024 NM
Friction and mass moment is 0.0064 NM
The spring moment is almost four times higher then the shutter moment and prevents shutter from being stuck open.

(2) No back-up power is connected to the solenoid.

(3) Solenoid Data

Manufacturer Densintron Control Systems Ltd.
Unit 4, Airport Trading Estate
Biggin Hill, Kent, TN16 3BW, England
Tel : +44 01959 700100
Fax : +44 01959 700300

Description Rotary Solenoid

P/N F401-30-287RE

Reliability RE Type- Extended life : 10 million cycles

History of usage This component was include in a similar product device named V_TransACT Rod Unit (p/n 473-3102-0207) .The device is still being evaluated by NRC.

Note : see data sheet in appendix D .
The shutter mechanism based on solenoid (different type) was also used in a similar device named TransACT Rod Unit (NRC registration No. NR-1032-D-101-S)

(4)Attached in appendix C test report 475-3201-0005 of the shutter radiation safety and reliability. The test report 475-3685-0002 was based on 2,500 cycles/year which was not corrected.

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.

All the application information including its appendicies are clasified as non-proprietary documentation. In spite of proprietary marks appeared on a number of drawings, please refer them as NON - PROPRIETARY.

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

Attached in appendix D the drawings bellow :

Rod Bold Position	**drawing**	**No. 119040006**
Shutter Locking Lever		
(Rod shutter actuator screw)	**drawing**	**No. 119040047**
Locker Screw	**drawing**	**No. 562-3102-0605**

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.

The temperature on both ends and middle of the source holder does not reaches 40°c. We conclude , according to the glue specifications (3M #2216 epoxy), that under normal operating conditions, the glue won't chemically break down and the source won't break loose from its holder. See MG ATC Source Holder Temperature Test Report (No. TRP000051AA) in appendix C.

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.

The Gd-153 sealed line source is glued by DuPont to a grove on the source holder (see drawings No. 14 in appendix A of the original submission file, page A-18). The information about the gluing procedure, materials and methodology, is described in page D-3 of appendix D of the original submission file. The void space left between the "line source" and the "source lead finish" after gluing was planned to compensate the production tolerances of the components.

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

The dimensions of the side walls in the rod source house are:

height, 3.2mm.
thickness, 3.8mm.

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

Attached in Appendix E, 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."

Attached in Appendix D, the revised engineering draw of Label 1.
See appendix A , updated MG ATC Operation Manual , pp. 2-10,2-11.

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).

Attached in Appendix D, the revised engineering draw of Label 1.
See appendix A , updated MG ATC Operation Manual , pp. 2-10,2-11.

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

The maximum installation height for the device is 1.3 meter.

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

Generally, the radiation exposure from a line gamma emitter source depends linearly on source activity. The radiation profile values provided in application corresponded to new (nominal) source received from manufacturer. Since the radiation measurements of the prototype were implemented with decayed Gd153 source (half life is 242 days), the measured values were referred to nominal activity as following:

Rnom = Rmeas * 450/297, where

Rnom - radiation exposure rate for source with nominal activity of 450 mCi;
Rmeas - measured radiation exposure rate for source with decayed activity of 297 mCi;
450 mCi - nominal activity of the source;
297 mCi - actual activity of the decayed source at the time when measurements were taken;

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.

(1) Attached in Appendix F, a copy of current ISO 9001 certificate for Elgems.
(2) Appendices A and B include all the necessary instructions for the use, inspection and installation of the MG ATC option. These user and service manuals are distributed to each customer that purchases the option. The manuals are GE's, not ELGEMS's as we uncorrectly noted on the original submission.

13. In the Service Manual, (1) complete the sentence for the 1 Rad in the second paragraph on page 1-5, (2) correct 50Ci 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."

Attached in Appendix A, updated MG ATC Operation Manual.
Attached in Appendix B, updated MG ATC Service Manual.

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

Attached in Appendix G, the NER-462 Source Window Safety Evaluation received from DuPont.

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

According to ANSI N542-1977, the device considered as Medical Radiography is not required for vibration test (tables 1 and 4).

We performed Basic Transportation Test (page G-9 in the original submission) in order to check the effect of shipment of the rod to the site and measured no radiation leakage after inserting the line source (see Effect of Transportation on Transmission Line Source Radiation Leakage, page 11 on the original submission file).

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

No special procedures for installation of the components are necessary.

Appendix A

MG ATC Operation Manual