

FOI as

From: "Beebe, Jim (MED)" <James.Beebe@amermsx.med.ge.com>
To: "Bhachu, Ujagar" <usb@nrc.gov>
Date: Mon, Aug 2, 1999 9:04 AM
Subject: a list of hospitals

Hello, Ujagar

Although this is not your area, I am writing to you because I know you and hope that you can tell me whom I should contact.

I would like to know how I can obtain a list of hospitals and clinics that have an NRC license to have/use radioactive materials on their premises.

Thank you for your help.

Regards,

Wm. J. NRC (FOI)

Received: from igate ([148.184.176.31])
by smtp (GroupWise SMTP/MIME daemon 4.1 v3)
; Mon, 2 Aug 99 09:03:54 EDT

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by smtp-gateway ESMTPœ id JAA24090
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Message-ID: <CF5F534E19FED01186050060B0670BFC043BADE8@USWAUMSX03MEDGE>
From: "Beebe, Jim (MED)" <James.Beebe@amermsx.med.ge.com>
To: "Bhachu, Ujagar" <usb@nrc.gov>
Subject: a list of hospitals
Date: Mon, 2 Aug 1999 08:04:38 -0500
Return-Receipt-To: "Beebe, Jim (MED)" <James.Beebe@amermsx.med.ge.com>
X-Mailer: Internet Mail Service (5.5.2448.0)

ELGEMS

P.O.Box 170 – Tirat Hacarmel 30200 ISRAEL

Tel 972-4-8563666 – Fax 972-4-8577663

Dear reviewer Mr. Seung Lee,

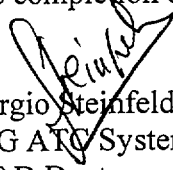
19/7/99

According to your letter to Mr. Beebe dated on July 7,1999, we send you the attached file with the required information to continue the review and evaluation of MG ATC Rod Unit p/n ASM 000415.

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

I would also like to inform you that we received the k number K991896 of the MG ATC system submission to the FDA for 510K approval.

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

We are in the process of reviewing your application for ATC Rod Unit p/n ASM 000415 Model. However, in order to continue our review, we need the following information :

1. For the MA-0476-S-117-S dated April 1, 1999,
 - a. Please state how the effect of two source "L" deployment and Tc-99m transmission on the bonding capability of the epoxy were taken into consideration.

See response on 1.b

- b. Please specify how the working life of the source was established. It appears in the application that the bonding capability of the epoxy was evaluated using a single source.

The Gd-153 source bonding capabilities is depended on the source self-irradiation only. The interference between the two Gd153 sources and influence of the external one (which can be only patient with administrated radiopharmaceutical) is negligible. Each Gd-153 source designed as beam limited device and attached to camera detector as shown in Service Manual, Figure 1-1. Each source equipped with lead shielding and collimator provided strictly narrow and parallel radiation beam as shown in Appendix F of original submission, Transmission Source Radiation Profile, Page F-3. In addition, the two source "L" deployment provides no interference between the sources. The radiation dose superposition has effect only inside Transmission Field of View area between the source rods where patient body should be located.

The Gd-153 source bonding capabilities was estimated on basis of DuPont approved NER-462 Fe-55 source evaluation(see appendix D of the original submission , page D-3), which contains irradiation test results of the epoxy for expected life of the source of 5 years.

- c. Please clarify how the manufacturing tolerance. The note 8 in Attachment 2 states that "Minimum and maximum dimensions shown are nominal values, this standard tolerances <not to exceed $\pm .12$ > apply to each dimension. However, in the block, the tolerances are specify as ± 0.10 and ± 0.05 for .xx and .xxx respectively. What tolerance is used for ATC Rod Unit. ?

Note 8 states the tolerances used.

2. Please provide the external radiation profiles as well as radiation exposure for workers and other personnel when the patient, already injected either Tl-201 or Tc-99m, is inside the radiation beams.

Both emission radiation emitted from patient body and transmission radiation emitted from transmission sources determine the radiation exposure for workers and other personnel. According to device prototype evaluation test results (see Appendix F of the original submission file, page F-3, Transmission Source Rod Radiation Profile Test), the maximal transmission exposure from both sources does not exceed 0.02 mR/h outside transmission field of view (page F-5, §2 of Test Results). The typical value of radiation exposure is less than 0.01 mR/h. Therefore, the radiation dose from transmission sources per nuclear medicine cardiac procedure (where the device is intended to be used) is $0.01 \times 15 / 60 = 0.0025$ mR, where 15 min is usual procedure duration. One can conclude the transmission radiation emitted from transmission sources is comparable to regular radiation background and considered as negligible.

The emission radiation emitted from patient body and reached nuclear medicine department personnel (in terms of nuclear medicine facility – technologist) is use to be much higher. For radiation worker in a nuclear medicine department, the annual effective dose received is generally of the order of 200 mR. Specifically, radiation dose to nuclear medicine technologists in cardiac procedure is 0.35 mR (Nuclear Medicine in Clinical Diagnosis and Treatment. Edited by I.P.C. Murray, ..., 1998, pp.1659,1670).

Finally, the radiation dose addition to worker and other personnel in a nuclear medicine department caused by transmission source radiation is less than 1%. The dose from both emission and transmission radiation is not be exceed 10 CRF Part 20 occupational and public dose limits.

3. Please provide the radiation levels and exposure rates during other conditions of use, such as leak testing , calibration, etc.

The occupational exposure during loading and unloading of the sources is less than 0.04 mR (see Test Report in Appendix F , page F-13 of original submission). When leak testing to be performed the occupational exposure is considered to be comparable to background level (see Appendix F of the original submission, Transmission Source Rod Radiation Profile Test – page F-5, §3)

4. Please provide the training requirements for field engineers to remove, replace, install, and repair of the Rod Units.

Qualified field

The ~~GE~~ field engineers should be take part of the MG ATC Option course in the GE Training center in Milwaukee.

5. Please provide the requirements and qualifications for the device users.

No special requirements and qualifications are required for the device users over regular requirements for operating nuclear medical equipment.

6. Please provide the corrected warning statement in Service Manual page 5-4.

Attached corrected page 5-4.

Updated Pages of the MG ATC Service Manual:

List of Revisions

Page 5-4

LIST OF REVISIONS

ECO	REV	DATE	DESCRIPTION	PAGES	APPROVED BY
	0	April 1999	Procedures for fitting the ATC option to the Millennium MG system.	All	Sergio Steinfeld
	1 Provisional	May 1999	Corrections requested by NRC	1-5, 1-10, 1-11, 3-7, 5-2, & 5-4	Sergio Steinfeld
	1	July 1999	Corrections requested by NRC	5-4	Sergio Steinfeld

5. Hold the empty Source Container in vertical position, shake it to slide the piston outwards, and then replace it on the table. Insert the rectangular end of the Plunger into the top of the piston protruding from the Source Container. Holding the protruding section firmly, secure the fastening nut in a CW direction (Step 1 in Figure 5-4).
6. Push the plunger half the way in Step 2 in Figure 5-4).
7. Line up an empty Lead-Shielded Source Container to the Rod Unit, using the locating pin protruding from the Source Container to ensure correct alignment with the Rod Unit (see Step 3 in Figure 5-4).
8. Secure the empty Source Container to the Rod Unit, using one of original screws removed at Step 3, above (see Step 4 in Figure 5-4).
9. Push the Plunger all the way in, and carefully turn the plunger fully CW (Step 5 in Figure 5-4).
10. Pull out the Plunger, extracting the source holder from the Rod Unit into the Lead-shielded Source Container (Step 6 in Figure 5-4).
11. While holding the Piston, remove the Plunger by turning the fastening Nut CCW.
12. Reassemble the Cover Plate on the free end of the Source Container.
13. Disassemble the Source Container from the Rod Unit (Step 7 in Figure 5-4).
14. Reassemble the Cover Plate on the other end of the Source Container.
15. Discard the source container with the expended source as per the local regulations for radioactive materials.

**WARNING**

Disposal of the used line sources must be in accordance with the regulatory procedures. Only GE trained personnel or someone licensed by NRC or an Agreement State are considered suitable for source disposal

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19/7/99

Dear reviewer Ujagar S. Bhachu ,

According to your letter to Mr. Beebe dated on June 30,1999, we send you the attached file with the required information to continue the review and evaluation of V_TransACT Rod Unit system.

We would like to clarify the history of the V_TransACT Rod Unit system submission:

- 25 March 1998, GE submitted V_TransACT Rod Unit system application.
- 19 January 1999, First deficiency letter was sent from NRC.
- 16 February 1999, the response on first deficiency was sent to NRC.
- 30 June 1999, Second deficiency letter was sent from NRC.

The answers and explanations are reference to the same paragraph numbers of the enclosure 1 attached to Mr. Camper letter .


The following appendices were include

Appendix 1 – Copy of 510k approval for V_TransACT
Copy of current ISO 9001 certificate for Elgems

Appendix 2 – Copy Of MIL STD 810 514.3 Procedure I
Copy of IEC 601-1 clauses 28 & 22
Copy of Solenoid data sheet

Appendix 3 – Updated MG ATC Operation Manual
Updated pages of MG ATC Service Manual.

Appendix 4 - Appendix H & J of Original Submission File of
March, 1998



Sergio Steinfeld
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1.0 GENERAL

- 1.1 The V-TransACT device is intended to be used under general license.

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

- 2.1 Attached in appendix 1, a copy of the 510K approval for VTransACT we sent you on September 4, 1998.
- 2.2 In DuPont memo issued on January 28, 1999, the maximum activity loading for the NES-8429 Gd-153 V_TransACT Line Source of 540 mCi means +20% of nominal activity. All sources are loaded to a nominal 450 mCi, having an upper tolerance of +20% and lower tolerance of -10% as specify in note 1 of registration certificate Attachment 1. This source registration was submitted for a maximum activity of 600 mCi for model NES-8429.
- 2.3 The V-TransACT Gd-153 source bonding capabilities is depended on the source self-irradiation only. The interference between the two Gd153 sources and influence of the external one (which can be only patient with administrated radiopharmaceutical) is negligible. Each Gd-153 source designed as beam limited device and attached to camera detector as shown in Appendix C of original submission, V-TransAct Service Manual, Figure 1-4. Each source equipped with lead shielding and collimator provided strictly narrow and parallel radiation beam as shown in Appendix F of original submission, Transmission Source Radiation Profile, Page F-11 and Appendix C of response on 1st deficiency letter, Transmission Source Rod Radiation Profile Test.
In addition, the two source "L" deployment at 90° provides no interference between the sources. The radiation dose superposition has effect only inside Transmission Field of View area between the source rods where patient body should be located
- 2.4 The V-TransACT Gd-153 source bonding capabilities was estimated on basis of DuPont approved NER-462 Fe-55 source evaluation, which contains irradiation test results of the epoxy after 2.5×10^7 Grays of Sr-90/Y-90 radiation. The total absorbed dose to the epoxy of the Gd-153 source is calculated to be 2.0×10^5 Grays over the working life of the source, which is by 2 orders less than evaluated one. The Gd-153 source emits only gamma photons at two energy ranges of 41 – 47 keV (70%) and 97 – 103 keV (30%). The Sr-90/Y-90 source contains gamma radiation of 558 keV (95%) and beta radiation of 546 keV (100%) and 2284 keV (100%). The radiation damage of epoxy glue caused by such radiation (gamma-rays and electrons) is considered independent on radiation spectrum. In such systems the radiation energy is deposited homogeneously and absorbed dose is expressed in terms of

"Grays" (*General consideration of the radiation chemistry of polymers. A. Chapiro / Nucl. Instr. and Meth. In Phys. Res. B 105 (1995) 5-7*).

- 2.5 Note 8 states the tolerances used.
- 2.6 According to our request, the source manufacturer DuPont has provided the following information: "The maximum activity loading for the NES-8429 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%".
- 2.7 Both emission radiation emitted from patient body and transmission radiation emitted from transmission sources determine the radiation exposure for workers and other personnel. According to device prototype evaluation test results (see Appendix C of response on 1st deficiency letter, Transmission Source Rod Radiation Profile Test), the maximal transmission exposure from both sources does not exceed 0.02 mR/h outside transmission field of view (page 3, §2 of Test Results). The typical value of radiation exposure is less than 0.01 mR/h. Therefore, the radiation dose from transmission sources per nuclear medicine cardiac procedure (where the device is intended to be used) is $0.01 \times 15 / 60 = 0.0025$ mR, where 15 min is usual procedure duration. One can conclude the transmission radiation emitted from transmission sources is comparable to regular radiation background and considered as negligible.

The emission radiation emitted from patient body and reached nuclear medicine department personnel (in terms of nuclear medicine facility – technologist) is use to be much higher. For radiation worker in a nuclear medicine department, the annual effective dose received is generally of the order of 200 mR. Specifically, radiation dose to nuclear medicine technologists in cardiac procedure is 0.35 mR (Nuclear Medicine in Clinical Diagnosis and Treatment. Edited by I.P.C. Murray, ..., 1998, pp.1659,1670).

Finally, the radiation dose addition to worker and other personnel in a nuclear medicine department caused by transmission source radiation is less than 1%. The dose from both emission and transmission radiation is not be exceed 10 CRF Part 20 occupational and public dose limits.

3.0 TEST REPORT – APPENDIX "C"

- 3.1/2 According to ANSI N542-1977, the device considered as Medical Radiography is not required for vibration test (tables 1 and 4).

In spite of that, in order to check the effect of shipment of the rod to the site and ensure that there is no radiation leakage after inserting the line source, we

performed Basic Transportation Test (page G-9 in the original submission) (see test report Effect of Transportation on Transmission Line Source Radiation Leakage G-8).

Attached in appendix 2 , a copy of the standard used : MIL-STD-810D, Method 514-3 Procedure I

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 25 thousands 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 . See attached in appendix 2 a copy of IEC-601 -1 , clauses 28 & 22)

The solenoid chosen, dynamic component (see attached in appendix 2 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 shutter solenoid mechanism was tested for 2,500 operations , the equivalent for one year of use and no failures were observed (see on appendix G , test report V_TransACT Shutter). The solenoid was also tested for 100,000 open/close cycles (equivalent to 40 years life) on a similar device (see 3.3).

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

3.3 Solenoid History of usage (attached in appendix 2 data sheet of the solenoid)

This component and similar shutter arrangement was include in a similar product device named MG ATC Rod Unit (p/n ASM 000415) which is still being evaluated by NRC. The reliability test performed on that device consisted on 100,000 open/close cycles which is equivalent of 40 years life of the V_TransACT solenoid mechanism.

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)

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 shutter mechanism does not include ball bearings.

4.0 OPERATION MANUAL

- 4.1 The pages that have been added/updated are : List of Revisions, page TC-4, page 2-12, page 3-3, page 3-12, chapter 4, page 6-1 and page 6-2 . Attached in appendix 3 the updated copy of the Operation Manual.
- 4-2 ^{Qualified} ~~The GE field~~ engineers should be take part of the ^{VTransACT} ~~MG-ATC~~ Option course in the GE Training Center in Milwaukee.

5-0 SERVICE MANUAL

- 5-1 All of these symbols in section 1.6, subsection 1.6.1, IEC Symbols, are given in standard UL2601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety, Second Edition, Clause 6. UL2601-1 is the relevant Underwriters Laboratory standard for nuclear medicine equipment, including the labels. Compliance to the UL standard is recognized by the FDA as one of their requirements for FDA clearance (510(k)) to market the NM device in the USA
- 5-2 Chapter 1-8-page 1-11 (not page 1-8 as specified) was updated . EN60601-1-2 was changed to the international standard IEC-601-1-2. Please replace the attached updated pages (List Of Revisions, page 1- 10/11) attached in appendix 3 on the Service Manual. *There is no a*

6-0 QUALITY ASSURANCE

- 6-1 Package 1 (Nonproprietary documentation) file is the responds to NRC clarifications required on January 1999, of our original submission of March 1998. This file does not include appendix H and I which are part of the original submission. *There is no appendix J.*

Despite of that , we attached again, in appendix 4 , both appendix H & I of the original submission file.

- 6-2 Attached in appendix 1, a copy of ISO 9001 certification.

- 6-3 GE qualified service engineers are responsible of the quality assurance for the loading and unloading of devices and sources. As part of the installation, radiation leakage test should be done as specify in the Service Manual page 3-26.

After the installation, the camera should be checked for radiation leaks at least once every six month or earlier stipulated by local safety regulations as specify in Operation Manual, Maintenance , page 5-12.

No other measurements are required to be taken to assure conformance with specifications of the device radiation profiles.

7-0 REGULATORY REQUIREMENTS

- 7-1 The V-TransACT application satisfies the regulatory requirement of 10 CFR 32.71 and requirements of 10 CFR 20, Subpart J..B';.
- 7-2 The occupational exposure during loading and unloading of the sources is less than 0.04 mR (see Test Report in Appendix F, page F-19 of original submission). When leak testing to be performed the occupational exposure is considered to be comparable to background level (see Appendix C of response on 1st deficiency letter, Transmission Source Rod Radiation Profile Test – page 3, §3)

Mr. Thomas A. Demeke
Regulatory Programs Manager
General Electric Medical System
P.O. Box 1414, W-641
Milwaukee, WI 53201-0414.

Dear Mr. Demeke:

We have reviewed your application dated March 8, 1998, requesting registration of the V-Transact Rod Unit-Attenuation System to be manufactured by Elgems and marketed by GE Medical Systems and Elcint Inc. In reviewing the application information, we find the application is lacking the required information. Therefore, we request that you forward to us the following information so that we can continue the review and evaluation of your application.

1.0 A Request for Withholding of Information

- 1.1 By affidavit, signed by Mr. Nathan Hermony and certified by a General Counsel, you requested Nuclear Regulatory Commission (NRC) to withhold from public information appearing in Appendices 'A', 'B' & 'C', of your application binder.

Pursuant to your request we reviewed your application and material in accordance with the requirements of 10 CFR 2.790. We are unable to grant your blanket request for withholding of information as stated in your application. We have determined that only certain portions of the requested information to be withheld contain trade secrets, and proprietary commercial information. In general, only that information which cannot be obtained through observations or measurements of components or documentation obtainable by a member of the public can be withheld as proprietary material.

With regards to engineering drawings, information generally considered being proprietary includes information such as dimensional tolerances, technical specifications of materials, manufacturing notes or specific assembly directions. Any remaining information on the drawings would be released. Please identify specific information on each drawing that you wish to withhold as proprietary, and provide nonproprietary versions in accordance with 10CFR 2.790(b)(1)(ii).

Operational and service manuals are normally provided to the purchasers of the equipment. We are unable to grant at this time that the information contained in these manuals is proprietary. Based on this finding you may wish to address the contents of these manuals. Please provide NRC with proprietary and nonproprietary packages or marked documents. An affidavit attested by Notary Public must be submitted prior to the staff making its final determination. The revised affidavit and documents must be submitted to the NRC within 30 days from the date of this letter, if not in accordance with 10 CFR 2.790 (c) the information sought to be withheld will be placed in the Commissions Public Document Room.

- 1.2 10 CFR 2.790 (9) (V) requires that an assessment be made of substantial harm to the competitive position of the owner taking in to account the value of the information to the owner. Please provide the estimated effort or money expended by the owner in developing the information, and the ease and difficulty with which the information could be properly acquired or duplicated.

2.0 Design & Drawings

- 2.1 The application states that the source to be used in the device is a Dupont model NES-8429, registration number NR-0476-S-117-S. However, the only models indicated in the registration certificate are NES-8412 through NES-8425.

We have read the letter from Dupont Pharma to Elgems, dated January, 1998, regarding an amendment to the device registration. However, as Dupont is located in an Agreement State, it will be necessary for Dupont's request to be addressed and processed by the Commonwealth of Massachusetts prior to the approval of the device, or for you to obtain approval from NRC for custom use of a source with a device. The custom source approval may be obtained by providing the information about a source to NRC as described in NUREG 1556 Vol. 3..

- 2.2 Radiation profiles for iso-distances are shown for single sources in the Appendix 'F' of the application. The application is for 'L' configuration and two source housing deployments would suggest that the above tests will yield significantly different results. Please submit actual radiation profiles reflecting the use of the source housing.
- 2.3 Please provide the specifications of the adhesive used to retain the sealed source in the aluminum source holder, in particular with respect to content, service life, and resistance to deterioration from radiation. Also please elaborate as to why the configuration of the aluminum source holder in contact with stainless steel will not create a galvanic cell, and include a description of the term "black oxide" as applied to the surface treatment of the aluminum per the engineering drawing.
- 2.4 Drawings submitted with the application do not address adequately the following:
- screw on shipping holder / housing interfaces
 - the plastic rod insertion tool / the source rod interface
 - how the plastic rod is held in place during installation by pressure, the means with which pressure is applied, and subsequently how the holder is closed
 - details of spring solenoid and shutter mechanism and its operations
 - explain the term, "captive screw"

We would appreciate receiving drawings and description which will clearly and concisely illustrate the above indicated areas and interfaces.

- 2.5 Not all the engineering drawings which were submitted indicate the units, and in some cases, e.g., portions of Detail "D" of drawing marked "A-22," End View on drawing marked "A-26" annotations appear in a foreign language. While many of the dimensions on the engineering drawings you supplied appear to be in millimeters (mm) there appears to be some mixed units on drawings marked "A-5" & "A-6" in the narrative and the drawings. Please resubmit these drawings which contain information in language other than English with the data in English, and verify the units of measurement for each drawing. It is not essential to convert units from metric, but the units should be consistent.
- 2.6 Please elaborate on the built in design elements that will not allow an incorrect indication of the shutter position.

- 2.7 Manual shutter levers are installed on both the assemblies. Please confirm that the operator will be able to see the lever position of both the shutters during normal operations.
- 2.8 Is this application also for a mobile van unit, if so, please explain how the unit has been designed and tested to maintain its integrity during transportation.
- 2.9 Section 3.3.10 of your application includes a maintenance responsibility matrix. Please define the type and the extent of maintenance to be undertaken by the user and/or vendor.
- 2.10 Please describe what additional inspection GE will undertake to ensure the integrity of the device received from Israel.

3. Operational Procedures.

- 3.1 Page 2-2 Item 9 deals with a malfunction of a device or as a result of an accident situation. We recommend that you list the telephone and fax number, of the service office, on this page in bold letters. This will ensure speedy access.

4.0 Testing

- 4.1 The source mechanism is tested by sensing the position of two slotted switches mechanically attached to the tungsten rod shutter which indicates whether the shutter is open or closed. Please provide the means and method of attachment of the switch. Also, provide NRC with the test data that establishes the reliability and failure rate acceptance criteria for the switch.

5.0 Service Manual

On Page 1- 4. Please re-word the label as it appears to direct the user to look into the source aperture. It should read " indicator window"

On Page 2-2. Please define, "parked position."

6.0 Prototype Testing

- 6.1 Please define the type of drop test conducted. A visual test as primary test following a drop test of the source is not acceptable. A leak test or survey must be done to assure the integrity of the source and source housing. Please submit the leak tests or survey results.

Please confirm whether the drop test performed as a part of the prototype tests, which you have stated were in accordance with ANSI N542-1997, were the class 2 drop test's Table therein. In particular state whether the test was performed as indicated per table 1 (10 times to a steel surface from a height of 1.5m) and section 7.4.3 of the standard.

7.0 Test Report

7.1 Please demonstrate how vibration test are satisfactory for the transportation of the device from Israel to USA locations.

7.2 Please provide a copy of Standard EN46001 in the English language.

8 Work In Progress

The application states in a number of places that work is in progress, i.e., Trouble Shooting (Page 5-1), Adjustments to Rods, QC Procedures (Page 6-8) and Mechanical adjustments, Planned Maintenance Page 6-8). Please provide complete final manuals.

Please respond within 30 days of the date of this letter and be certain to address all the areas of concern cited herein. Please include sufficient information so that NRC is in a position to review the radioactive source as a custom use, or resubmit your application in its entirety that addresses all the issues in duplicate after you have obtained a copy of an approved registration certificate for the appropriate Dupont source.

If we can be of any assistance please do not hesitate to call me on (301)415-7894.

Sincerely,

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

Ditribution:
SSSS r/f

SSD-98-39

NEO1

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OFFICE	MSB	C	MSB						
NAME	USBhachu		CTRaddatz						
DATE	01/13/99		01/13/99						

OFFICIAL RECORD COPY

Dear Mr. Ujagar S. Bhachu

According to your letter to Mr. Demke dated on January 19, 1999, we send you the attached file with the required information to continue the review and evaluation of V-TransACT Rod Unit-Attenuation System.

The answers and explanations were inserted into your letter (**bold letters**) after each required clarification. Enclosed to this submission, two packages are attached: package 1 – Nonproprietary documentation and package 2 – Proprietary documentation.

The following appendices were include in each package:

Package 1 – Nonproprietary documentation

Appendix List

- A – Affidavit
- B – Du Pont Pharmaceuticals data.
 - Adhesive information
 - Registration Certificate.
- C – Prototype Testing
 - Transmission Source Rod Radiation Profile Test
 - V_TransACT Shutter Test Report
 - Transmission Rod Unit Drop Test - Report
 - Effect of Basic Transportation (vibration) on Transmission Source Rod Radiation Leakage
- D- V_TransACT Option Operator's Reference Manual
- E- V_TransACT Service Manual
- F – Engineering Drawings
- G – EN 46001 Standard

Package 2 – Proprietary documentation

Engineering drawing 761-3685-104

We would like to inform you that our new representative in GEMS is:
Mr. James E. Beebe , Ph.D.
X-ray Projects – Safety & Regulatory
Phone : 414-544-3889
Fax : 414-544-3061
E-Mail : James.Beebe@med.ge.com

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.

A handwritten signature in black ink, appearing to read 'Steinfeld', is written inside a hand-drawn triangular shape.

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

UNITED STATES

NUCLEAR REGULATORY COMMISSION

Washington, D.C. 20555-0001

January 19, 1999

Mr. Thomas A. Demeke

Regulatory Programs Manager
General Electric Medical System
P.O. Box 1414, W-641
Milwaukee, WI 53201-0414.

Dear Mr. Demeke:

We have reviewed your application dated March 8, 1998, requesting registration of V-TransACT Rod Unit-Attenuation System to be manufactured by Elgems and marked by GE Medical Systems and Elscint Inc. In reviewing the application information, we find the application is lacking the required information. Therefore, we request that you forward to us the following information so that we can continue the review and evaluation of your application.

1.0 A Request for Withholding of Information.

- 1.1 By affidavit, signed by Mr. Nathan Hermony and certified by a General Counsel, you requested Nuclear Regulatory Commission (NRC) to withhold from public information appearing in Appendices 'A', 'B' & 'C', of your application binder.

Pursuant to your request we reviewed your application and material in accordance with the requirements of 10 CFR 2.790. We are unable to grant your blanket request for withholding of information as stated in your application. We have determined that only certain portions of the requested information to be withheld contain trade secrets, and proprietary commercial information. In general, only that information which cannot be obtained through observations or measurement of components or documentation obtainable by a member of the public can be withheld as proprietary material.

With regards to engineering drawing, information generally considered being proprietary includes information such as dimensional tolerances, technical specifications of materials, manufacturing notes or specific assembly directions. Any

remaining information on the drawings would be released. Please identify specific information on each drawing that you wish to withhold as proprietary, and provide nonproprietary versions in accordance with 10CFR 2.790(b)(1)(ii).

Operational and service manuals are normally provided to the purchasers of the equipment. We are unable to grant at this time that the information contained in these manuals is proprietary. Based on this finding you may wish to address the contents of these manuals. Please provide NRC with proprietary and nonproprietary packages or marked documents. An affidavit attested by Notary Public must be submitted prior to the staff making its final determination. The revised affidavit and documents must be submitted to the NRC within 30 days from the date of this letter, if not in accordance with 10 CFR 2.790 (c) the information sought to be withheld will be placed in the Commissions Public Document Room.

- 1.2 10 CFR 2.790 (9) (V) requires that an assessment be made of substantial harm to the competitive position of the owner taking into account the value of the information to the owner . Please provide the estimated effort or money expended by the owner in developing the information, and the ease and difficulty with which the information could be properly acquired or duplicated.

Enclosed in appendix A, the updated affidavit declaration.

2.0 Design & Drawings.

The application states that the source to be used in the device is Dupont model NES-8429, registration number NR-0476-S-117-S. However , the only models included in the registration certificate are NES-8412 through NES -8425.

We have read the letter from Dupont Pharma to Elgems , dated January, 1998, regarding an amendment to the device registration. However, as Dupont is located in an Agreement State, it will be necessary for Dupont's request to be addressed and processed by the Commonwealth of Massachusetts prior to the approval of the device, of for you to obtain approval from NRC for custom use of a source with a device. The custom source approval may be obtained by providing the information about a source to NRC as described in NUREG 1556 Vol. 3.

Enclosed in appendix B (pages 3 ÷ 9) the registrations certificate for Du Pont Merck Pharmaceuticals, dated on 6/11/98 and number No. MA-0476-S-117-S, which includes model NES – 8429.

Radiation profiles for iso-distances are shown for single sources in the appendix F of the application. The application is for 'L' configuration and two source housing deployments would suggest that the above tests will yield significantly different results. Please submit actual radiation profiles reflecting the use of the source housing.

Enclosed in appendix C the actual radiation profiles report reflected the superposition of the radiation exposure obtained from the both sources.

Please provide the specifications of the adhesive used to retain the sealed source in the aluminum source holder, in particular with respect to content, service life, and resistance to deterioration from radiation. Also please elaborate as to why the configuration of the aluminum source holder in contact with stainless steel will not create a galvanic cell, and include a description of the term "black oxide" as applied to the surface treatment of the aluminum per the engineering drawing.

Enclosed in appendix B (page 2) the information regarding the adhesive used by Du Pont to fix the source into its holder.

The source holder is made of carbon steel SAE 1020 (see manufacturing drawing A-22 in appendix F) and not of aluminum as was incorrectly described in the original submission file. The black oxide treatment applied on it, is a corrosion protective treatment complying with MIL-C-13924 CLASS 1 standard.

Drawings submitted with the application do not address adequately the following:

Screw on shipping holder/housing interfaces
the plastic rod insertion tool/the source rod interface
how the plastic rod is held in place during installation by pressure, the means with which pressure is applied, and subsequently how the holder is closed

All the above issues are related to the mounting/exchanging procedures of the line source into the Rod Unit. A detailed description of the instructions and drawings for mounting/replacing the line source is written in the appendix E – V_TransACT Service Manual, section 3.2.7 and section 6.1.2 (updated Service Manual).

A set of mechanical drawings of the parts involved were included in appendix H of the original submission file (drawings H-4 ÷ H17). The following list of engineering part names and their representative names in the Manual will be helpful :

Source Container – Assy 18 Draw. No. 119170000 (H-4).

Cover Plate – Rod Zvill Cover Inside Draw. No. 11904101 (H-5).

Piston – Rod Zvill Buhna Draw No. 119040107 (H-10)
Aluminum Plunger – Rod Zvill Bush Draw. No. 11904108
(H-11). Note: this part was described in the prior application, by mistake, as a plastic rod.

The installation procedure concept is based on the following main steps:

- a) Mounting the Source Container to the Rod Unit after removing the cover plates from both units.
- b) Screwing the plunger to the piston, which was already screwed to the source holder by the source manufacturer. There is no need of any pressure, just inserting the rectangular end of the plunger into the piston protruding and securing the fastening plunger nut in the CW direction.
- c) Pushing the plunger all the way in, transferring the Source Holder into the Rod Unit. When the Holder is properly located inside, the mark on the plunger is in line with the end of the source container.
- d) Turning the Aluminum plunger CW to unlock the Source Holder from the piston and pulling both the plunger and piston all the way out.
- e) Releasing the plunger from the piston by turning it CCW and replacing the end cover plates.

The exchange procedure is based on the same concept.
Note : Detailed instructions and drawings can be found in sections 3.2.7. and 6.1.2 in the V_TransACT Service Manual (appendix E)

All the Source Container is safely shielded containing lead parts along the tube and on both ends.

details of spring solenoid and shutter mechanism and its operations.

Details of spring solenoid

The solenoid is a 45 degrees rotary type with front shaft extension and return spring provided. The expected life information provided by the manufacturer is 2 million cycles.

Shutter Mechanism – Reference to appendix A – Engineering drawings of the original submission file.

The tungsten bar is assembled to the Rod Clamp Inside (see drawings A10 and A14) which is attached to the solenoid shaft. When the solenoid is not energized, the tungsten bar is positioned between the collimator and the source holder blocking the transmission radiation (see drawings A-12 and A-15). Because the non-centered position of the tungsten bar referenced to the solenoid axis shaft, the bar will perform a rotation displacement of 45° when the solenoid is energized.

At that position the tungsten bar moves away between the collimator and the source holder allowing transmission of the radiation (see drawings A-13 and A-16).

explain the term, "captive screw"

The term "captive screw" was a wrong description of the type of screws on the device. The build in design of the device is based on structural screws which are not intended to be unscrewed by the user or service engineer.

We would appreciate receiving drawings and description which will clearly and concisely illustrate the above indicated areas and interfaces.

Not all the engineering drawings which were submitted indicate the units , and in some cases, e.g., portions of Detail "D" of drawing marked "A-22," End View on drawing marked "A-26" annotations appear in a foreign language. While many of the dimensions on the engineering drawings you supplied appear to be in millimeters (mm) there appears to be some mixed units on drawings marked "A-5" & "A-6" in the narrative and the drawings. Please resubmit these drawings which contain information in language other than English with the data in English, and verify the units of measurement for each drawing. It is not essential to convert units from metric , but the units should be consistent.

Attached to appendix F, the corrected A-22, A-26, A-5 and A-6 drawings.

Please elaborate on the built in design elements that will not allow an incorrect indication of the shutter position.

The following description is referenced to appendix F – Rod Assy No. 473-3102-0207/C 9 pages.

The shutter blocking Tungsten cylinder bar is mechanically attached to two clamps : "Rod Clamp Inside" (see part 6 of drawing 473-3102-0207/page 5), attached to the solenoid shaft

and "Rod Clamp Cover Outer" (see part 8 of drawing 473-3102-0207/page 6) at the back end of the Rod. The Tungsten is screwed to both clamps after rotating them to a specific position defined by the contact of two stopping pins (see part 15 of drawing 473-3102-0207/page5 and part 12 of drawing 473-3102-0207/page6) and two adjustable set screws preliminary calibrated to $21.8 \text{ mm} \pm 0.1$ and $16.7 \text{ mm} \pm 0.1$ (see part 9 of drawing of drawing 473-3102-0207/page 4 and part 7 of drawing 473-3102-0207/page 6). This position assures that the tungsten bar is in front of the source house blocking the radiation when the solenoid is not energized.

On the "Rod Clamp Cover Outer", a Lever indicator pin (see part 13 of drawing 473-3102-0207/page 6) is screwed indicating the open and close position of the shutter when the solenoid is energized or not.

The proper assembly of the tungsten bar on both clamps, as described, enables screwing this Lever indicator pin.

The design ensures that there is only one possible mechanical way to screw the Lever pin, to assure the correct indication of the shutter position according to the label symbols aside the Lever window.

Attached to the "Rod Clamp Inside", a "Rod Plate Position" (see part 8 of drawing 473-3102-0207/page 5) rotates between two static slotted optical switches, assembled on an aluminum bracket (see 473-3102-0207/page 3), which senses both shutter positions : shutter close and shutter fully open.

The design ensures that is only one possible way to assemble the Rod Plate Position part, to assure, after proper assembly of the tungsten bar on both clamps, the correct location of the "Rod Plate Position" part according to the shutter position.

The design ensures that there is only one possible way to assemble the aluminum bracket, holding both optical switches, (see draw 473-3102-0207/page 4) which assures the correct position detection of the shutter sensed by the optical switches when the Rod Plate is rotated between them.

In case of wrong assembly or calibration of the "Rod Clamp Inside", the "Rod Plate Position" part will be out of its nominal place and all the system operation will be unable to activate.

Manual shutter levers are installed on both the assemblies. Please confirm that the operator will be able to see the lever of both the shutters during normal operations.

Standing on any side of the Gantry, the operator is able to see at least the lever of one shutter. There are places where he can see the levers of both the shutters.

Is this application also for a mobile van unit, if so, please explain how the unit has been designed and tested to maintain its integrity during transportation.

This application will not be used for a mobile van unit.

Section 3.3.10 of your application includes a maintenance responsibility matrix. Please define the type and the extent of maintenance to be undertaken by the user and/or vendor.

Maintenance to be done by the user

The device maintenance activities to be done by the user are explained in the appendix D, V_TransACT Option - Operator's Reference Manual , chapter 5 – Maintenance as follows :

- 1) Cleaning Parts of the V-TransACT Option – page 5-11
- 2) Radioactive Contamination Test – page 5-12

Maintenance to be done by the vendor

The device maintenance activities to be done by the vendor are explained in appendix E, V_TransACT - Service Manual, as follows :

- 1) Source Replacement – page 6-1
- 2) Beeper Test – page 6-8
- 3) Transmission Source Holder Radiation Leakage Test, as part of the System Calibration and Adjustment – section 4.6.7 and part of Quality Control procedures – page 6-8 .

Please describe what additional inspection GE will undertake to ensure the integrity of the device received from Israel.

The integrity of the device received from Israel is checked during the V_TransACT system installation according to the following instructions in the V_TransACT Service Manual (appendix E) :

- 1) Hardware Installation, chapter 3. Paragraph 3.2.6/g -
Assembling the V_TransACT Rod Units
This test is done without the line source assembled and includes checking the proper mechanism of the shutter.
- 2) Hardware Installation, chapter 3. Paragraph 3.2.9 -
Radiation Leakage Test.

The camera is checked, performing a dry wipe test, for radiation leaks.

3) System Calibration and Adjustment, chapter 4 .Section 4.6 – Performance Measurement and Testing (V_TransACT QC)

Specifically section 4.6.7 Source Holder Radiation Leakage Test.

This test is used to measure the residual radiation leakage at the external surface of the Rods, while the shutter is closed.

3.0 Operational Procedures.

Page 2-2 Item deals with a malfunction of a device or as a result of an accident situation. We recommend that you list the telephone and Fax number office, on this page in bold letters. This will ensure speedy access.

We added in the V_TransACT Operator's Reference Manual (appendix D) page 2.2 and 2.8 the telephone and Fax number office.

4.0 Testing.

The source mechanism is tested by sensing the position of two slotted switches mechanically attached to the tungsten rod shutter which includes whether the shutter is open , provide NRC with the test data that establishes the reliability and failure rate acceptance criteria for the switch.

The two slotted switches sense both positions of the tungsten rod shutter :

- closed position, when one switch is "On" and the second "Off" i.e. the radiation from the line source is blocked**
- and fully open position when the first switch is "Off" and the second "On", the radiation is emitted out through the collimator.**

A plate, connected to the rotational clamp, moves between the optical switches when the solenoid is energized or not.

The shutter test, performed every power_on of the system, performs a three stages cycle (close/open/close) of the shutter mechanism checking the right status of both optical switches at each stage.

Furthermore, the optical switches are on line monitored by the system, also when the V_TransACT option is not working , in order to assure the normally shutter close position.

Reliability and diagnostic tests

The report results of the shutter mechanism reliability , diagnostics and power failure safe-fail can be found on appendix C, V_TransACT Shutter - test report.

The failure rate acceptance criteria for the slotted switch is zero. The life test successfully performed on the shutter, a 2500 times open/close cycle, equals to 12 month life without any failure.

5.0 Service Manual.

On Page 1-4. Please re-word the label as it appears to direct the user to look into the source aperture. It should read "indicator window" .

On page 2-2. Please define, "parked position".

Find the above changes in the updated Service Manual (appendix E).

6.0 Prototype Testing.

Please define the type of drop test conducted. A visual test as primary test following a drop test of the source is not acceptable . A leak test or survey must be done to assure the integrity of the source and source housing. Please submit the leak tests or survey results.

Please confirm whether the drop test performed as a part of the prototype tests, which you have stated were in accordance with ANSI N542-1997 , were the class 2 drop test's Table therein. In particular state whether the test was performed as indicated per table 1(10 times to a steel surface from a height of 1.5m) and section 7.4.3 of the standard.

Enclosed in appendix C the Transmission Rod Unit Drop Test report implemented in accordance with ANSI N542-1977 class 2 including leak and survey test results.

7.0 Test Report.

Please demonstrate how vibration test are satisfactory for the transportation of the device from Israel to USA locations.

The transportation of both the device and the source container to the site is done separately. The device, not including the line source, is transported from Israel. The source container, which includes the source holder with the line source glued, is transported from the Du Pont Pharmaceuticals to the site, on a

shipping box in compliance with U.S. Department of Transportation packaging specifications for USA DOT 7A Type A radioactive material (49CFR 178.350).

In order to demonstrate how vibration test are satisfactory for the transportation of the device to the site, we measure the transmission line source radiation leakage on a device that have being performed a Basic Transportation Test , using a source holder (with a line source glued) sent by Du Pont from the USA on a type A package.

The Basic Transportation Test done on the device without the source holder, complies standard MIL-STD-810D, Method 514.2 Procedure 1.

Enclosed in C the following documents :

- a) Effect Of Basic Transportation (vibration) on Transmission Source Rod Radiation Leakage - Report.
- b) Environmental Laboratory – test Report of Basic Transportation of the V_TransACT device.
- c) Copies of commercial invoice and information of the line sources package type sent to Israel.

Please provide a copy of Standard EN46001 in the English language.

Enclosed in appendix G a copy of Standard EN46001.

8.0 Work In Progress.

The application states in a number of places that work is in progress, i.e., Trouble Shooting (Page 5-1), Adjustments to Rods , QC Procedures (Page 6-8) and Mechanical adjustments, Planned Maintenance (Page 6-8). Please provide complete final manuals.

Enclosed in appendix D the complete final V_TransACT Operator's` Reference Manual .

Enclosed in appendix E the complete final V_TransACT Service Manual.

Please respond within 30 days of the date of this letter and be certain to address all the areas of concern cited herein. Please include sufficient information so that NRC is in a position to review the radioactive source as a custom use, or resubmit your application in its entirety that addresses with the issues in duplicate after you have obtained a copy of an approved registration certificate for the appropriate Dupont Source.

If we can be of any assistance please do not hesitate to call me on
(301)415-7894

Sincerely,

Ujagar S. Bhachu, Mechanical Engineer
Materials Safety Branch,
Division of Industrial and Office of Nuclear Safety and Safeguards.

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 Appendix '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"

514.7.

- 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.
- 3.2 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 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 ²1-8) 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 *Section (page 1-11)*
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.

From: "Traegde, Kenath" <Kenath.Traegde@rcp.dph.state.ma.us>
To: "usb@nrc.gov" <usb@nrc.gov>
Date: Wed, Jun 9, 1999 10:37 AM
Subject: Amendment Date 4/1/99 for Certificate MA-0476-S-117-S

Ujagar,

Attached is the latest amendment per your request. The new diagrams are also attached.

Also, in partial answer to your questions, the diagram for the 4/1/99 amendment shows the 400 mCi source as an inset for Model Number NES_8424. The Model you are interested in was 8429.

All sources identified in this certificate are of the same design. The only difference is the length of the source and the source strength.

Please call me at (617)727-6214 x2027 if you need any further assistance.

Ken Traegde
6/9/99

<<ma-0476-s-117-s-scanned-converted.wpd>>

January 19, 1999

Mr. Thomas A. Demeke
Regulatory Programs Manager
General Electric Medical System
P.O. Box 1414, W-641
Milwaukee, WI 53201-0414.

Dear Mr. Demeke:

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- 2.2 Radiation profiles for iso-distances are shown for single sources in the Appendix 'F' of the application. The application is for 'L' configuration and two source housing deployments would suggest that the above tests will yield significantly different results. Please submit actual radiation profiles reflecting the use of the source housing.
- 2.3 Please provide the specifications of the adhesive used to retain the sealed source in the aluminum source holder, in particular with respect to content, service life, and resistance to deterioration from radiation. Also please elaborate as to why the configuration of the aluminum source holder in contact with stainless steel will not create a galvanic cell, and include a description of the term "black oxide" as applied to the surface treatment of the aluminum per the engineering drawing.
- 2.4 Drawings submitted with the application do not address adequately the following:
- screw on shipping holder / housing interfaces
 - the plastic rod insertion tool / the source rod interface
 - how the plastic rod is held in place during installation by pressure, the means with which pressure is applied, and subsequently how the holder is closed
 - details of spring solenoid and shutter mechanism and its operations
 - explain the term, "captive screw"

We would appreciate receiving drawings and description which will clearly and concisely illustrate the above indicated areas and interfaces.

- 2.5 Not all the engineering drawings which were submitted indicate the units, and in some cases, e.g., portions of Detail "D" of drawing marked "A-22," End View on drawing marked "A-26" annotations appear in a foreign language. While many of the dimensions on the engineering drawings you supplied appear to be in millimeters (mm) there appears to be some mixed units on drawings marked "A-5" & "A-6" in the narrative and the drawings. Please resubmit these drawings which contain information in language other than English with the data in English, and verify the units of measurement for each drawing. It is not essential to convert units from metric, but the units should be consistent.
- 2.6 Please elaborate on the built in design elements that will not allow an incorrect indication of the shutter position.

- 2.7 Manual shutter levers are installed on both the assemblies. Please confirm that the operator will be able to see the lever position of both the shutters during normal operations.
- 2.8 Is this application also for a mobile van unit, if so, please explain how the unit has been designed and tested to maintain its integrity during transportation.
- 2.9 Section 3.3.10 of your application includes a maintenance responsibility matrix. Please define the type and the extent of maintenance to be undertaken by the user and/or vendor.
- 2.10 Please describe what additional inspection GE will undertake to ensure the integrity of the device received from Israel.

3. Operational Procedures.

- 3.1 Page 2-2 Item 9 deals with a malfunction of a device or as a result of an accident situation. We recommend that you list the telephone and fax number, of the service office, on this page in bold letters. This will ensure speedy access.

4.0 Testing

- 4.1 The source mechanism is tested by sensing the position of two slotted switches mechanically attached to the tungsten rod shutter which indicates whether the shutter is open or closed. Please provide the means and method of attachment of the switch. Also, provide NRC with the test data that establishes the reliability and failure rate acceptance criteria for the switch.

5.0 Service Manual

On Page 1- 4. Please re-word the label as it appears to direct the user to look into the source aperture. It should read "indicator window"

On Page 2-2. Please define, "parked position."

6.0 Prototype Testing

- 6.1 Please define the type of drop test conducted. A visual test as primary test following a drop test of the source is not acceptable. A leak test or survey must be done to assure the integrity of the source and source housing. Please submit the leak tests or survey results.

Please confirm whether the drop test performed as a part of the prototype tests, which you have stated were in accordance with ANSI N542-1997, were the class 2 drop test's Table therein. In particular state whether the test was performed as indicated per table 1 (10 times to a steel surface from a height of 1.5m) and section 7.4.3 of the standard.

January 19, 1999

7.0 Test Report

7.1 Please demonstrate how vibration test are satisfactory for the transportation of the device from Israel to USA locations.

7.2 Please provide a copy of Standard EN46001 in the English language.

8 Work In Progress

The application states in a number of places that work is in progress, i.e., Trouble Shooting (Page 5-1), Adjustments to Rods, QC Procedures (Page 6-8) and Mechanical adjustments, Planned Maintenance Page 6-8). Please provide complete final manuals.

Please respond within 30 days of the date of this letter and be certain to address all the areas of concern cited herein. Please include sufficient information so that NRC is in a position to review the radioactive source as a custom use, or resubmit your application in its entirety that addresses all the issues in duplicate after you have obtained a copy of an approved registration certificate for the appropriate Dupont source.

If we can be of any assistance please do not hesitate to call me on (301)415-7894.

Sincerely,

original signed by Ujgar Bhachu

Ujgar S. Bhachu, Mechanical Engineer
Materials Safety Branch,
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards.

Ditribution:

SSSS r/f SSD-98-39 NEO1
NRC Central file IMNS r/f NMSS r/f

DOCUMENT NAME: P:\ELGEMSFC.WPD

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OFFICE	MSB	<input checked="" type="checkbox"/>	MSB					
NAME	USBhachu <i>usb</i>		CTRaddatz					
DATE	01/13/99		01/14/99					

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I N T E R

MEMO

O F F I C E

To: Steve Baggett, Section Leader, SSSS / SCSB / IMNS / NMSS / USNRC
From: George R. Cicotte ODH
Subject: REVIEW OF ELGEMS' V_TRANSACT REGISTRATION UNDER SSD ON-THE-JOB TRAINING
Date: December 9, 1998

It will not be possible to complete the draft of this registration certificate until ELGEMS provides updated information. I decided that since they needed to respond anyway, and rather than go to the administrative issue of drafting a memorandum to file, I would go ahead and ask about the aluminum/steel interface.

File numbers are VTRANS.SSD and VTRANS.DEF.

Sincerely,

George R. Cicotte
Health Physicist 3
Nuclear Materials Safety Section
Bureau of Radiation Protection
Division of Prevention
Ohio Department of Health

GE Medical Systems

8000 Grandview Blvd.
Waukesha, WI 53188
MB 641

September 4, 1998

Mr. Steve Bagget
U.S Nuclear Regulatory Commission
Materials Safety Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

Subject: 510K approval for VTransACT with NRC Assignment Number 98-39

Dear Mr. Baggett:

Attached is the FDA 510K approval letter for the VTransACT. This clears the FDA requirements such as safety for US marketing of this product.

The NRC safety evaluation of the VTransACT is now needed in order to market the product. I would appreciate any information as to the status of this application. Please contact me by phone (414-547-4759) or mail.

Sincerely Yours;



Lawrence Hause, Ph.D.
GE Safety and Regulatory Engineering



GE Medical Systems

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

3 February, 1999

Ujagar S. Bhachu, Mechanical Engineer
Materials Safety Branch, Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Bhachu,

We request a 30 day extension in the response deadline contained in your letter of 19 January, 1999, to GE Medical Systems, concerning our product VTransACT.

Elgems Engineering is working on responses to the eight sections in your letter. Two items in section 2.0 concern our supplier Dupont Pharma. While we are in communication with Dupont, we do not have a commitment from them. One item concerns a custom source from Dupont. We believe Dupont already has a certificate for this model. The second item is the specifications of the adhesive used to retain the sealed source in the aluminum source holder, again, information we expect from Dupont.

A handwritten signature in cursive script that reads 'James E. Beebe'.

James E. Beebe, Ph.D.
Safety and Regulatory for X-Ray, Nuclear Medicine & PET

Tel: 414-544-3061
Pager: 414-558-7686
Fax: 414-548-5197



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 4 1998

Yair Friedman
VP- Quality and Regulatory Affairs
Elgems Ltd.
P.O. Box 170
Tirat Hacarmel 30200
Israel

Re: K980959
VTransACT: Attenuation Correction System
for Dual-Head Variable-Angle Gamma Camera
Dated: March 12, 1998
Received: March 16, 1998
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Friedman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/ocrh/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

May 29, 1998

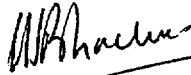
Philip J. Frappaola, Deputy Director
Office of Compliance
Center for Devices and Radiological Health
Department of Health and Human Services
Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850

Dear Mr. Frappaola:

As agreed upon in the Memorandum of Understanding between the Nuclear Regulatory Commission (NRC) and the Food and Drug Administration (FDA), we are informing FDA that NRC has received an application for registration of a product that may be regulated by both Agencies. The applicant indicated that it has notified FDA. Please see the enclosure to this letter which includes a brief description of the application.

If you have any questions, please contact me at (301) 415-7894 or Mr. Steven Baggett at (301) 415-7273.

Sincerely,



Ujagar Bhachu, Mechanical Engineer
Materials Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: Description of Application

Distribution:



SSSS r/f
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SSD-98-39
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NEO1 

DOCUMENT NAME: C:\WINDOWS\TEMP\DOC4.WPD

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OFFICE	MSB	<input checked="" type="checkbox"/>	MSB 	<input checked="" type="checkbox"/>					
NAME	UBhachu 		SBaggett						
DATE	05/28/98		5/28/98						

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ENCLOSURE

ELGEMS V-TransACT Rod Unit-Attenuation Correction System.

Applicant's Name and Address	Elgems Ltd. Tirat Hacamel, Israel.
Contact Name	Tom Demke
Contact Telephone Number	1-414-544-3915
Source or Device	Device / V-TransAct
Isotope	Gadolinium 153
Activity	Two Housing Unit- Total 900 mCi
Intended Use	General Medical Use -Code V.
New Application or Amendment	New Application.
Date of the Application	March 25, 1998
<p>Brief Description of the Application: A Dual Head Nuclear Medicine Imaging System. The device is installed on the base unit which is mounted to a dual head camera gantry. Two source housing bases are permanently mounted to the gantry and rotate with the gantry during tomography scan. Step and Shoot and attenuation options provide the means to factor in body tissues attenuation affects to the CT Scans and SPECT Images.</p>	

NRC FORM 567
(8-93)

U. S. NUCLEAR REGULATORY COMMISSION

**REQUEST FOR A SEALED SOURCE OR
DEVICE EVALUATION**

FK
** Check attached*

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 <i>GE Medical Systems</i>		REGION/LOCATION: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> HQ <input type="checkbox"/> LFCB	
TELEPHONE NUMBER	DATE	TYPE OF ACTION REQUESTED (Check as appropriate)	
APPLICANT'S NAME <i>Tom Demke</i>		<input checked="" type="checkbox"/> SOURCE REVIEW	<input type="checkbox"/> AMENDMENT OF REGISTRATION SHEET NUMBER(S)
MAIL CONTROL NUMBER(S)		<input checked="" type="checkbox"/> DEVICE REVIEW	
LETTER/APPLICATION DATE	LICENSE NUMBER(S)	<input type="checkbox"/> CUSTOM REVIEW	

COMMENTS: *3000 NORTH GRAND VIEW BLVD. WAUKESHA, WI 53188*

FOR SSSS USE ONLY

REVIEWER	MODEL NUMBERS <i>V-TRANSACT</i>	NUMBER ASSIGNED <i>98-39</i>
DATE RECEIVED <i>3/30/98</i>	DATE ASSIGNED	DATE TO FEES <i>3/30/98</i>

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)
<input checked="" type="checkbox"/> NEW AMENDMENT	<input checked="" type="checkbox"/> NEW AMENDMENT	<input type="checkbox"/> NEW AMENDMENT	<input type="checkbox"/> NEW AMENDMENT
<input type="checkbox"/> NO SAFETY EVALUATION REQUIRED <input type="checkbox"/> NO FEES REQUIRED		<input type="checkbox"/> LICENSING ACTION REQUIRED IF KNOWN	
		YES NO	
<input type="checkbox"/> OTHER (Specify)			

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

FOR BILLING PURPOSES ONLY

<input type="checkbox"/> NAME CHANGE	<input type="checkbox"/> ADDRESS CHANGE	<input type="checkbox"/> NEW REGISTRATION - ADD TO BILLING	<input type="checkbox"/> PRODUCT INACTIVE - REMOVE FROM BILLING
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FOR FEE USE ONLY

TYPE OF FEE <i>APP</i>	FEE CATEGORY <input checked="" type="checkbox"/> 9A <input type="checkbox"/> 9B <input type="checkbox"/> 9C <input type="checkbox"/> 9D		
AMOUNT RECEIVED <i>\$37.00</i>	CHECK NUMBER <i>0013173092</i>	<input type="checkbox"/> MATANN UPDATED AS REQUIRED	
DATE OF CHECK <i>3/24/98</i>	LOG <i>Am 9815540</i>	<input type="checkbox"/> MATSYS UPDATED AS REQUIRED	
APPROVED BY <i>sh</i>	DATE RETURN <i>4/2/98</i>	DATE	

COMMENTS

NRC FORM 567
(8-93)

U. S. NUCLEAR REGULATORY COMMISSION

REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

KK
** Check attached*

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 <i>GE Medical Systems</i>		REGION/LOCATION: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> HQ <input type="checkbox"/> LFDCB			
TELEPHONE NUMBER	DATE	TYPE OF ACTION REQUESTED (Check as appropriate)			
APPLICANT'S NAME <i>Tom Demke</i>		<input checked="" type="checkbox"/> SOURCE REVIEW		<input type="checkbox"/> AMENDMENT OF REGISTRATION SHEET NUMBER(S)	
MAIL CONTROL NUMBER(S)		<input checked="" type="checkbox"/> DEVICE REVIEW			
LETTER/APPLICATION DATE		<input type="checkbox"/> CUSTOM REVIEW			
LICENSE NUMBER(S)					

COMMENTS: *3000 NORTH GRAND VIEW BLVD.
WAUKESHA, WI 53188*

FOR SSSS USE ONLY

REVIEWER	MODEL NUMBERS <i>V-TRANSACT</i>	NUMBER ASSIGNED <i>98-39</i>
DATE RECEIVED <i>3/30/98</i>	DATE ASSIGNED	DATE TO FEES <i>3/30/98</i>

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)
<input checked="" type="checkbox"/> NEW AMENDMENT	<input checked="" type="checkbox"/> NEW AMENDMENT	<input type="checkbox"/> NEW AMENDMENT	<input type="checkbox"/> NEW AMENDMENT
<input type="checkbox"/> NO SAFETY EVALUATION REQUIRED <input type="checkbox"/> NO FEES REQUIRED		<input type="checkbox"/> LICENSING ACTION REQUIRED IF KNOWN	
		YES NO	
<input type="checkbox"/> OTHER (Specify)			

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

FOR BILLING PURPOSES ONLY

<input type="checkbox"/> NAME CHANGE	<input type="checkbox"/> ADDRESS CHANGE	<input type="checkbox"/> NEW REGISTRATION -- ADD TO BILLING	<input type="checkbox"/> PRODUCT INACTIVE -- REMOVE FROM BILLING
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FOR FEE USE ONLY

TYPE OF FEE <i>APP</i>	FEE CATEGORY <input checked="" type="checkbox"/> 9A <input type="checkbox"/> 9B <input type="checkbox"/> 9C <input type="checkbox"/> 9D		
AMOUNT RECEIVED <i>\$37.00</i>	CHECK NUMBER <i>0013193092</i>	<input type="checkbox"/> MATANN UPDATED AS REQUIRED	
DATE OF CHECK <i>3/24/98</i>	LOG <i>Apr 98 15540</i>	<input type="checkbox"/> MATSYS UPDATED AS REQUIRED	
APPROVED BY <i>JK</i>	DATE RETURN <i>4/2/98</i>	DATE	

COMMENTS

REV
3/2/98 RC

March 25, 1998

Mr. John Lubinski
United States Nuclear Regulatory Commission
Sealed Source Safety Section
Division of Industrial and Medical Nuclear Safety
Washington, D.C. 20555-0001

Subject: Device Registration For V_TransACT Attenuation Correction Option

Dear Mr. Lubinski:

GE Medical Systems and Elscint Inc. intend to market the Attenuation Correction Option (V_TransACT) for use on their dual head Nuclear Medicine Imaging Systems. This option will be manufactured by ELGEMS Ltd., which is a joint venture of GE Medical Systems and Elscint. This application is submitted for the purposes of NRC conducting a radiation safety evaluation and registration of this device, which is designed to contain by-product material. The 510(k) application was submitted to FDA on March 12, 1998.

The information contained within this application follows the format in Regulatory Guide 10.10, March 1987, U.S. Nuclear Regulatory Commission. The registration fee of \$3700 is enclosed.

If you have any questions regarding this application, please feel free to contact Tom Demke (414 544-3915) or myself.

Sincerely,



Glenn Stricklin
Manager, Nuclear Operations
Tel: (414) 544-3270
Fax: (414) 548-5197

CLIENT BUSINESS SERVICES, INC.
 PO BOX 60500
 FORT MYERS FL 33906-6500

As Disbursing Agent for: GE MEDICAL SYSTEMS

CHECK NO.
 0013173092

51-44
 119

DATE OF CHECK
03/24/98

PAY: Three Thousand Seven Hundred And No/100 Dollars

CHECK AMOUNT
\$3,700.00

TO THE ORDER OF: UNITED STATES NUCLEAR
 REGULATORY COMMISSION
 OFF OF NUCLEAR MAT SAF & SAFEG
 WASHINGTON DC 20555-

[Handwritten Signature]
 Authorized Signature

Shawmut Bank Connecticut, N.A. Hartford, Connecticut.

⑈0013173092⑈ ⑆011900445⑆ 46493⑈

PAGE 01

Control # 353

CLIENT BUSINESS SERVICES, INC.
 PO BOX 60500
 FORT MYERS FL 33906-6500
 (941) 418-5060

As Disbursing Agent for: GE MEDICAL SYSTEMS

<- Please direct all inquiries to this vendor service line. Our Automated Service Line Has Improved !!!!!
 Favor dirigir cualquier pregunta al numero de telefono indicado. Nuestra Linea Automatica de Servicio a Vendedores Ha Mejorado!!!!

UNITED STATES NUCLEAR
 REGULATORY COMMISSION
 OFF OF NUCLEAR MAT SAF & SAFEG
 WASHINGTON DC 20555-

INVOICE NUMBER	DATE	VOUCHER	GROSS AMOUNT	DISCOUNT	NET AMOUNT
RQ032098S7 DEVICE REGISTRATION	03/20/98	AHD0S7	3700.00	0.00	3700.00
CHECK NUMBER	DATE	VENDOR NO.	NAME	TOTAL AMOUNT	
0013173092	03/24/98	475528-00	UNITED STATES NUCLEAR	\$ 3700.00	

U.S. Nuclear Regulatory Commission
For Credit to U.S. Treasury
ALC #31-00-0001

April 2, 1998

ASSIGNMENT NUMBER: 98-39

Mr. Tom Demke
G.E. Medical Systems
3000 North Grand View Blvd.
Waukesha, WI 53188

SUBJECT: ACKNOWLEDGMENT OF REQUEST FOR SAFETY EVALUATION

Dear Mr. Demke:

This letter acknowledges the receipt of your March 25, 1998, application that requested an amendment to the safety evaluation of Model V_TransACT. We have performed a cursory review of your application and determined that enough information has been provided to allow a technical reviewer to initiate the evaluation process. Applications are assigned to technical reviewers on a first-in basis. Therefore, your application will be assigned in turn. Please note that the technical reviewer may contact you to request information that was omitted from your application or to obtain clarification of technical issues concerning your application. If you have any questions concerning the status of your application, please contact me at (301) 415-8140. Please reference the assignment number listed above in your questions or correspondence.

Please be aware that your request may be subject to the NRC's application fees in accordance with 10 CFR Part 170. Therefore, a copy of your application has been forwarded to the License Fee and Debt Collection Branch for approval of the fee category and amount. If you have any questions concerning the fees associated with your application, please contact the License Fee and Debt Collection Branch at (301) 415-7554.

Sincerely,

ISR

KimBerly Randall, Registration Assistant
Materials Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Distribution:

IMNS r/f SSD-98-39
SBaggett NE01

DOCUMENT NAME:P:98-39.wpd

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OFFICE	MSB								
NAME	KRandall <i>KR</i>								
DATE	4/2/98								

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(9-94)
NRCMD 3.5

PUBLIC MEETING ANNOUNCEMENT DATA INPUT

(Fields with shaded headings are mandatory)

NEW
 REVISED

NRC MEETING CONTACT

NAME	COMMERCIAL TELEPHONE (Include Area Code)	FACSIMILE TELEPHONE (Include Area Code)
UJAGAR S. BHACHU & SEUNG LEE	(301) 415 - 7894	(301) 415 - 5369

MEETING DATE(S) AND TIME(S) (up to three entries)

MEETING DATE(S) (Use MM/DD/YY format)		MEETING TIME(S) (Circle a.m. or p.m.)			
FROM	TO	BEGINNING		ENDING	
7/19/99	7/19/99	2:00	<input type="checkbox"/> a.m. <input checked="" type="checkbox"/> p.m.	4:30	<input type="checkbox"/> a.m. <input checked="" type="checkbox"/> p.m.
			<input type="checkbox"/> a.m. <input type="checkbox"/> p.m.		<input type="checkbox"/> a.m. <input type="checkbox"/> p.m.
			<input type="checkbox"/> a.m. <input type="checkbox"/> p.m.		<input type="checkbox"/> a.m. <input type="checkbox"/> p.m.

MEETING LOCATION

BUILDING	TWO WHITE FLINT NORTH	STREET ADDRESS	11545 ROCKVILLE PIKE
ROOM NUMBER	T-10A3	CITY AND STATE	ROCKVILLE, MARYLAND

PURPOSE OF MEETING (96 characters available)

GE/ELGEMS TO REVIEW WITH NRC STAFF THEIR APPLICATIONS FOR MEDICAL IMAGING DEVICES.

COMMENTS (96 characters available)

APPLICANT MAY REQUEST THIRD PARTY EXCLUSION FROM PROPRIETARY RELATED PROCEEDINGS

**MEETING
(CHECK ONE)**

PUBLIC
 NON-PUBLIC

DOCKET OR PROJECT NUMBER and/or FACILITY NAME

99-23 & 99-39

ORGANIZATIONS IN ATTENDANCE

NRC OFFICES/REGIONS (Offices only – DO NOT use Divisions, Branches, etc.)	OUTSIDE PARTICIPANTS (Company/Licensee/Agency Names – avoid abbreviations)
NMSS, OGC	GE MEDICAL SYSTEMS MILWAULKEE, WI.

APPROVAL – (Required for fewer than 10 calendar days advance notice)

SIGNATURE -- BRANCH CHIEF 	DATE 7-14-99
--	-----------------

RETURN THIS FORM TO: MEETING NOTICE COORDINATOR, MAIL STOP T-6 D8
FACSIMILE (301) 415-5130, TELEPHONE (301) 415-7092, E-MAIL: PMNS

Dear Mr. Ujagar S. Bhachu

According to your letter to Mr. Demke dated on January 19,1999, we send you the attached file with the required information to continue the review and evaluation of V-TransACT Rod Unit-Attenuation System.

The answers and explanations were inserted into your letter (**bold letters**) after each required clarification. Enclosed to this submission, two packages are attached: package 1 – Nonproprietary documentation and package 2 – Proprietary documentation.

The following appendices were include in each package:

Package 1 – Nonproprietary documentation
Appendix List

- A – Affidavit
- B – Du Pont Pharmaceuticals data.
 - Adhesive information
 - Registration Certificate.
- C – Prototype Testing
 - Transmission Source Rod Radiation Profile Test
 - V_TransACT Shutter Test Report
 - Transmission Rod Unit Drop Test - Report
 - Effect of Basic Transportation (vibration) on Transmission Source Rod Radiation Leakage
- D- V_TransACT Option Operator's Reference Manual
- E- V_TransACT Service Manual
- F – Engineering Drawings
- G – EN 46001 Standard

Package 2 – Proprietary documentation

Engineering drawing 761-3685-104

We would like to inform you that our new representative in GEMS is:
Mr. James E. Beebe , Ph.D.
X-ray Projects – Safety & Regulatory
Phone : 414-544-3889
Fax : 414-544-3061
E-Mail : James.Beebe@med.ge.com

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.

A handwritten signature in black ink, appearing to read 'Steinfeld', enclosed within a hand-drawn triangular shape.

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

UNITED STATES

NUCLEAR REGULATORY COMMISSION

Washington, D.C. 20555-0001

January 19, 1999

Mr. Thomas A. Demeke

Regulatory Programs Manager
General Electric Medical System
P.O. Box 1414, W-641
Milwaukee, WI 53201-0414.

Dear Mr. Demeke:

We have reviewed your application dated March 8, 1998, requesting registration of V-TransACT Rod Unit-Attenuation System to be manufactured by Elgems and marked by GE Medical Systems and Elscint Inc. In reviewing the application information, we find the application is lacking the required information. Therefore, we request that you forward to us the following information so that we can continue the review and evaluation of your application.

1.0 A Request for Withholding of Information.

- 1.1** By affidavit, signed by Mr. Nathan Hermony and certified by a General Counsel, you requested Nuclear Regulatory Commission (NRC) to withhold from public information appearing in Appendices 'A', 'B' & 'C', of your application binder.

Pursuant to your request we reviewed your application and material in accordance with the requirements of 10 CFR 2.790. We are unable to grant your blanket request for withholding of information as stated in your application. We have determined that only certain portions of the requested information to be withheld contain trade secrets, and proprietary commercial information. In general, only that information which cannot be obtained through observations or measurement of components or documentation obtainable by a member of the public can be withheld as proprietary material.

With regards to engineering drawing, information generally considered being proprietary includes information such as dimensional tolerances, technical specifications of materials, manufacturing notes or specific assembly directions. Any

remaining information on the drawings would be released. Please identify specific information on each drawing that you wish to withhold as proprietary, and provide nonproprietary versions in accordance with 10CFR 2.790(b)(1)(ii).

Operational and service manuals are normally provided to the purchasers of the equipment. We are unable to grant at this time that the information contained in these manuals is proprietary. Based on this finding you may wish to address the contents of these manuals. Please provide NRC with proprietary and nonproprietary packages or marked documents. An affidavit attested by Notary Public must be submitted prior to the staff making its final determination. The revised affidavit and documents must be submitted to the NRC within 30 days from the date of this letter, if not in accordance with 10 CFR 2.790 (c) the information sought to be withheld will be placed in the Commissions Public Document Room.

- 1.2 10 CFR 2.790 (9) (V) requires that an assessment be made of substantial harm to the competitive position of the owner taking into account the value of the information to the owner . Please provide the estimated effort or money expended by the owner in developing the information, and the ease and difficulty with which the information could be properly acquired or duplicated.

Enclosed in appendix A, the updated affidavit declaration.

2.0 Design & Drawings.

The application states that the source to be used in the device is Dupont model NES-8429, registration number NR-0476-S-117-S. However , the only models included in the registration certificate are NES-8412 through NES –8425.

We have read the letter from Dupont Pharma to Elgems , dated January, 1998, regarding an amendment to the device registration. However, as Dupont is located in an Agreement State, it will be necessary for Dupont's request to be addressed and processed by the Commonwealth of Massachusetts prior to the approval of the device, of for you to obtain approval from NRC for custom use of a source with a device. The custom source approval may be obtained by providing the information about a source to NRC as described in NUREG 1556 Vol. 3.

Enclosed in appendix B (pages 3 ÷ 9) the registrations certificate for Du Pont Merck Pharmaceuticals, dated on 6/11/98 and number No. MA-0476-S-117-S, which includes model NES – 8429.

Radiation profiles for iso-distances are shown for single sources in the appendix F of the application. The application is for 'L' configuration and two source housing deployments would suggest that the above tests will yield significantly different results. Please submit actual radiation profiles reflecting the use of the source housing.

Enclosed in appendix C the actual radiation profiles report reflected the superposition of the radiation exposure obtained from the both sources.

Please provide the specifications of the adhesive used to retain the sealed source in the aluminum source holder, in particular with respect to content, service life, and resistance to deterioration from radiation. Also please elaborate as to why the configuration of the aluminum source holder in contact with stainless steel will not create a galvanic cell, and include a description of the term "black oxide" as applied to the surface treatment of the aluminum per the engineering drawing.

Enclosed in appendix B (page 2) the information regarding the adhesive used by Du Pont to fix the source into its holder.

The source holder is made of carbon steel SAE 1020 (see manufacturing drawing A-22 in appendix F) and not of aluminum as was incorrectly described in the original submission file. The black oxide treatment applied on it, is a corrosion protective treatment complying with MIL-C-13924 CLASS 1 standard.

Drawings submitted with the application do not address adequately the following:

Screw on shipping holder/housing interfaces
the plastic rod insertion tool/the source rod interface
how the plastic rod is held in place during installation by pressure, the means with which pressure is applied, and subsequently how the holder is closed

All the above issues are related to the mounting/exchanging procedures of the line source into the Rod Unit. A detailed description of the instructions and drawings for mounting/replacing the line source is written in the appendix E – V_TransACT Service Manual, section 3.2.7 and section 6.1.2 (updated Service Manual).

A set of mechanical drawings of the parts involved were included in appendix H of the original submission file (drawings H-4 ÷ H17). The following list of engineering part names and their representative names in the Manual will be helpful :

**Source Container – Assy 18 Draw. No. 119170000 (H-4).
Cover Plate – Rod Zvill Cover Inside Draw. No. 11904101 (H-5).**

Piston – Rod Zvill Buhna Draw No. 119040107 (H-10)
Aluminum Plunger – Rod Zvill Bush Draw. No. 11904108 (H-11). Note: this part was described in the prior application, by mistake, as a plastic rod.

The installation procedure concept is based on the following main steps:

- a) Mounting the Source Container to the Rod Unit after removing the cover plates from both units.
- b) Screwing the plunger to the piston, which was already screwed to the source holder by the source manufacturer. There is no need of any pressure, just inserting the rectangular end of the plunger into the piston protruding and securing the fastening plunger nut in the CW direction.
- c) Pushing the plunger all the way in, transferring the Source Holder into the Rod Unit. When the Holder is properly located inside, the mark on the plunger is in line with the end of the source container.
- d) Turning the Aluminum plunger CW to unlock the Source Holder from the piston and pulling both the plunger and piston all the way out.
- e) Releasing the plunger from the piston by turning it CCW and replacing the end cover plates.

The exchange procedure is based on the same concept.
Note : Detailed instructions and drawings can be found in sections 3.2.7. and 6.1.2 in the V_TransACT Service Manual (appendix E)
All the Source Container is safely shielded containing lead parts along the tube and on both ends.

details of spring solenoid and shutter mechanism and its operations.

Details of spring solenoid

The solenoid is a 45 degrees rotary type with front shaft extension and return spring provided. The expected life information provided by the manufacturer is 2 million cycles.

Shutter Mechanism – Reference to appendix A – Engineering drawings of the original submission file.

The tungsten bar is assembled to the Rod Clamp Inside (see drawings A10 and A14) which is attached to the solenoid shaft. When the solenoid is not energized, the tungsten bar is positioned between the collimator and the source holder blocking the transmission radiation (see drawings A-12 and A-15). Because the non-centered position of the tungsten bar referenced to the solenoid axis shaft, the bar will perform a rotation displacement of 45° when the solenoid is energized.

At that position the tungsten bar moves away between the collimator and the source holder allowing transmission of the radiation (see drawings A-13 and A-16).

explain the term, "captive screw"

The term "captive screw" was a wrong description of the type of screws on the device. The build in design of the device is based on structural screws which are not intended to be unscrewed by the user or service engineer.

We would appreciate receiving drawings and description which will clearly and concisely illustrate the above indicated areas and interfaces.

Not all the engineering drawings which were submitted indicate the units , and in some cases, e.g., portions of Detail "D" of drawing marked "A-22," End View on drawing marked "A-26" annotations appear in a foreign language. While many of the dimensions on the engineering drawings you supplied appear to be in millimeters (mm) there appears to be some mixed units on drawings marked "A-5" & "A-6" in the narrative and the drawings. Please resubmit these drawings which contain information in language other than English with the data in English, and verify the units of measurement for each drawing. It is not essential to convert units from metric , but the units should be consistent.

Attached to appendix F, the corrected A-22, A-26, A-5 and A-6 drawings.

Please elaborate on the built in design elements that will not allow an incorrect indication of the shutter position.

The following description is referenced to appendix F – Rod Assy No. 473-3102-0207/C 9 pages.

The shutter blocking Tungsten cylinder bar is mechanically attached to two clamps : "Rod Clamp Inside" (see part 6 of drawing 473-3102-0207/page 5), attached to the solenoid shaft

and "Rod Clamp Cover Outer" (see part 8 of drawing 473-3102-0207/page 6) at the back end of the Rod. The Tungsten is screwed to both clamps after rotating them to a specific position defined by the contact of two stopping pins (see part 15 of drawing 473-3102-0207/page5 and part 12 of drawing 473-3102-0207/page6) and two adjustable set screws preliminary calibrated to $21.8 \text{ mm} \pm 0.1$ and $16.7 \text{ mm} \pm 0.1$ (see part 9 of drawing of drawing 473-3102-0207/page 4 and part 7 of drawing 473-3102-0207/page 6). This position assures that the tungsten bar is in front of the source house blocking the radiation when the solenoid is not energized.

On the "Rod Clamp Cover Outer", a Lever indicator pin (see part 13 of drawing 473-3102-0207/page 6) is screwed indicating the open and close position of the shutter when the solenoid is energized or not.

The proper assembly of the tungsten bar on both clamps, as described, enables screwing this Lever indicator pin.

The design ensures that there is only one possible mechanical way to screw the Lever pin, to assure the correct indication of the shutter position according to the label symbols aside the Lever window.

Attached to the "Rod Clamp Inside", a "Rod Plate Position" (see part 8 of drawing 473-3102-0207/page 5) rotates between two static slotted optical switches, assembled on an aluminum bracket (see 473-3102-0207/page 3), which senses both shutter positions : shutter close and shutter fully open.

The design ensures that is only one possible way to assemble the Rod Plate Position part, to assure, after proper assembly of the tungsten bar on both clamps, the correct location of the "Rod Plate Position" part according to the shutter position.

The design ensures that there is only one possible way to assemble the aluminum bracket, holding both optical switches, (see draw 473-3102-0207/page 4) which assures the correct position detection of the shutter sensed by the optical switches when the Rod Plate is rotated between them.

In case of wrong assembly or calibration of the "Rod Clamp Inside", the "Rod Plate Position" part will be out of its nominal place and all the system operation will be unable to activate.

Manual shutter levers are installed on both the assemblies. Please confirm that the operator will be able to see the lever of both the shutters during normal operations.

Standing on any side of the Gantry, the operator is able to see at least the lever of one shutter. There are places where he can see the levers of both the shutters.

Is this application also for a mobile van unit, if so, please explain how the unit has been designed and tested to maintain its integrity during transportation.

This application will not be used for a mobile van unit.

Section 3.3.10 of your application includes a maintenance responsibility matrix. Please define the type and the extent of maintenance to be undertaken by the user and/or vendor.

Maintenance to be done by the user

The device maintenance activities to be done by the user are explained in the appendix D, V_TransACT Option - Operator's Reference Manual , chapter 5 – Maintenance as follows :

- 1) Cleaning Parts of the V-TransACT Option – page 5-11**
- 2) Radioactive Contamination Test – page 5-12**

Maintenance to be done by the vendor

The device maintenance activities to be done by the vendor are explained in appendix E, V_TransACT - Service Manual, as follows :

- 1) Source Replacement – page 6-1**
- 2) Beeper Test – page 6-8**
- 3) Transmission Source Holder Radiation Leakage Test, as part of the System Calibration and Adjustment – section 4.6.7 and part of Quality Control procedures – page 6-8 .**

Please describe what additional inspection GE will undertake to ensure the integrity of the device received from Israel.

The integrity of the device received from Israel is checked during the V_TransACT system installation according to the following instructions in the V_TransACT Service Manual (appendix E) :

- 1) Hardware Installation, chapter 3. Paragraph 3.2.6/g -
Assembling the V_TransACT Rod Units
This test is done without the line source assembled and includes checking the proper mechanism of the shutter.**
- 2) Hardware Installation, chapter 3. Paragraph 3.2.9 -
Radiation Leakage Test.**

The camera is checked, performing a dry wipe test, for radiation leaks.

3) System Calibration and Adjustment, chapter 4 .Section 4.6 – Performance Measurement and Testing (V_TransACT QC)

Specifically section 4.6.7 Source Holder Radiation Leakage Test.

This test is used to measure the residual radiation leakage at the external surface of the Rods, while the shutter is closed.

3.0 Operational Procedures.

Page 2-2 Item deals with a malfunction of a device or as a result of an accident situation. We recommend that you list the telephone and Fax number office, on this page in bold letters. This will ensure speedy access.

We added in the V_TransACT Operator's Reference Manual (appendix D) page 2.2 and 2.8 the telephone and Fax number office.

4.0 Testing.

The source mechanism is tested by sensing the position of two slotted switches mechanically attached to the tungsten rod shutter which includes whether the shutter is open , provide NRC with the test data that establishes the reliability and failure rate acceptance criteria for the switch.

The two slotted switches sense both positions of the tungsten rod shutter :

- closed position, when one switch is "On" and the second "Off" i.e. the radiation from the line source is blocked
- and fully open position when the first switch is "Off" and the second "On", the radiation is emitted out through the collimator.

A plate, connected to the rotational clamp, moves between the optical switches when the solenoid is energized or not. The shutter test, performed every power_on of the system, performs a three stages cycle (close/open/close) of the shutter mechanism checking the right status of both optical switches at each stage.

Furthermore, the optical switches are on line monitored by the system, also when the V_TransACT option is not working , in order to assure the normally shutter close position.

Reliability and diagnostic tests

The report results of the shutter mechanism reliability , diagnostics and power failure safe-fail can be found on appendix C, V_TransACT Shutter - test report.

The failure rate acceptance criteria for the slotted switch is zero. The life test successfully performed on the shutter, a 2500 times open/close cycle, equals to 12 month life without any failure.

5.0 **Service Manual.**

On Page 1-4. Please re-word the label as it appears to direct the user to look into the source aperture. It should read "indicator window" .

On page 2-2. Please define, "parked position".

Find the above changes in the updated Service Manual (appendix E).

6.0 **Prototype Testing.**

Please define the type of drop test conducted. A visual test as primary test following a drop test of the source is not acceptable . A leak test or survey must be done to assure the integrity of the source and source housing. Please submit the leak tests or survey results.

Please confirm whether the drop test performed as a part of the prototype tests, which you have stated were in accordance with ANSI N542-1997 , were the class 2 drop test's Table therein. In particular state whether the test was performed as indicated per table 1(10 times to a steel surface from a height of 1.5m) and section 7.4.3 of the standard.

Enclosed in appendix C the Transmission Rod Unit Drop Test report implemented in accordance with ANSI N542-1977 class 2 including leak and survey test results.

7.0 **Test Report.**

Please demonstrate how vibration test are satisfactory for the transportation of the device from Israel to USA locations.

The transportation of both the device and the source container to the site is done separately. The device, not including the line source, is transported from Israel. The source container, which includes the source holder with the line source glued, is transported from the Du Pont Pharmaceuticals to the site, on a

shipping box in compliance with U.S. Department of Transportation packaging specifications for USA DOT 7A Type A radioactive material (49CFR 178.350).

In order to demonstrate how vibration test are satisfactory for the transportation of the device to the site, we measure the transmission line source radiation leakage on a device that have being performed a Basic Transportation Test , using a source holder (with a line source glued) sent by Du Pont from the USA on a type A package.

The Basic Transportation Test done on the device without the source holder, complies standard MIL-STD-810D, Method 514.2 Procedure 1.

Enclosed in C the following documents :

- a) Effect Of Basic Transportation (vibration) on Transmission Source Rod Radiation Leakage - Report.
- b) Environmental Laboratory – test Report of Basic Transportation of the V_TransACT device.
- c) Copies of commercial invoice and information of the line sources package type sent to Israel.

Please provide a copy of Standard EN46001 in the English language.

Enclosed in appendix G a copy of Standard EN46001.

8.0 Work In Progress.

The application states in a number of places that work is in progress, i.e., Trouble Shooting (Page 5-1), Adjustments to Rods , QC Procedures (Page 6-8) and Mechanical adjustments, Planned Maintenance (Page 6-8). Please provide complete final manuals.

Enclosed in appendix D the complete final V_TransACT Operator's` Reference Manual .

Enclosed in appendix E the complete final V_TransACT Service Manual.

Please respond within 30 days of the date of this letter and be certain to address all the areas of concern cited herein. Please include sufficient information so that NRC is in a position to review the radioactive source as a custom use, or resubmit your application in its entirety that addresses with the issues in duplicate after you have obtained a copy of an approved registration certificate for the appropriate Dupont Source.