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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

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1.0 GENERAL

1.1 The V-TransACT device is intended to be used under ~~general~~ specific 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 2.5x107 Grays of Sr-90/Y-90 radiation. The total absorbed dose to the epoxy of the Gd-153 source is calculated to be 2.0x105 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 x 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 ~~The GE field~~ Qualified engineers should be take part of the ~~MG-A~~TC VT.TransACT 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)

Enclosure 1

ELGEMS V-TransACT

1.0 GENERAL

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

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

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

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

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

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

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

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

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

3.0 TEST REPORT- APPENDIX "C"

3.1 Please submit a copy of MIL-STD-810D, Method 514.~~2~~ 3 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 1-~~8~~ 2) 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.
Section (page 1-11)

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

6.0 QUALITY ASSURANCE

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

6.2 Please provide a copy of your ISO 9001 certification.

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

7.0 REGULATORY REQUIREMENTS

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

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