

ELGEMS

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Dear reviewer Mr. Seung Lee,

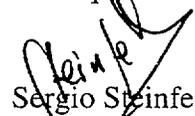
25/8/99

According to your letter to Mr. Beebe dated on August 13,1999, 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. Attached to the answers you will find the following material:

- a) updated MG AC Service Manual Rev. 3
- b) Engineering Drawings : No . MG ATC 101 (MG Gantry with ATC Option)
No. MG ATC 102 (MG Gantry at opposed position)
No. CBL000537 (ATC ROD CABLE)
No. ASM000415 (ROD Assy 6 drawings)
- c) Source Manufacturer (DuPont Pharma) performance Evaluation Sheet Test Report

We would like to thank you for your cooperation, answering our questions and clarifying the requested data.


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Questions from Sueng Lee (NRC), 13 August 1999,
re MG ATC

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. Please clarify the proposed registration certificate. Is it for (the) MG ATC Option whole system or (for the) MG ATC Rod Unit only?

The proposed registration certificate is for the MG ATC Rod Unit. As you already know, the MG ATC Option includes two MG ATC Rod units and all the Radiation Measurements (appendix G of the original submission file) were performed on the MG camera with the whole MG ATC Option assembled.

2. Please provide the rationale for the Rod Unit to be a source, (and) not to be a device as specified in the proposed registration certificate.

The MG ATC Rod unit is a device as specified in the proposed registration certificate. The NRC number should be NR- -D- -S.

3. Please provide the descriptions for the gantry and other devices to be attached to the gantry, including engineering drawings.

Note : Attached engineering drawings:

MG ATC 102 - MG Gantry at opposed position

MG ATC 101 - MG Gantry with ATC option at cardiac position

Gantry

The MG Gantry is a solid, floor mounted casting that provides mechanical support for the detectors and the MG ATC Option. The gantry consists of two concentric bearings that each support a detector. The axial drive motor powers the rotation of these bearings. An interlock mechanism will lock the bearings into either a 180 degree (opposed detectors) or 101.25 degree (cardiac position) configurations. The bearings allow the detectors to be rotated around the patient. The Gantry may be controlled by either the handset or by pulldown menus from the acquisition computer.

Detectors

The detectors are rectangular large field of view gamma radiation sensors (48 photomultiplier tubes per detector).

The detectors are design to detect gamma radiation and send the spatial and energy information about the radiation to the acquisition computer.

MG ATC Option

The MG ATC option includes two main units, the ATC Base Unit , attached to each head detector support plate, and the ATC Rod Unit assembled to each Base Unit. .

The ATC Base Unit consists on the mechanical Rod mounting and driving assembly.

The ATC Rod Unit includes a collimated radioactive source (Gd153, 450mCi), the lead shielded housing and the shutter mechanism.

The ATC Rod Unit is mounted on a carriage which travels along a linear track attached to a square beam mounted perpendicular on the detector support plate. This linear motion allows scanning transmission of the patient body detected by the opposite detector (cardiac position).

4. Please provide the description for two slotted switches (in Page 5 of 19) including locations and engineering drawings. How to differentiate between the first and the second switches?

Note : Attached engineering drawings:

**CBL000537 ATC ROD CABLE
ASM000415 ROD ASSY**

The purpose of the optical slotted switches is to enable the system to sense the shutter positions : shutter close, open and fully open.

The slotted switches DS605/6 cable (see ATC Rod Cable drawing CBL000537) is assembled to a static aluminum bracket (see assembling drawing ASM000415 page 4) which is screwed to the Rod Cover Adjustment part (see assembling drawing ASM000415 page 5&6, part 7).

A position plate (drawing ASM000415 page 4 part 24) is attached to a clamp (drawing ASM000415 page 4, part 23) which is screwed to the solenoid shaft. The position plate rotates between both slotted switches (see drawing ASM000415 page 5). The blocking tungsten bar (part 31) is attached to the same clamp.

According to the clamp rotation angle, the position is sensed by both switches. When the Tungsten bar blocks the radiation beam, DS605 is covered and DS606 is not (shutter close position). When the tungsten bar moves away of the blocking position, DS605 is uncovered (shutter open position). When the tungsten bar moves away to its maximum position, DS606 is covered (shutter fully open position).

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 cycle. Furthermore, the optical switches status is on line monitored by the system, also when the MG ATC option is not activated for assure the normally close position.

5. The application stated that GE personnel check the integrity of the Rod Unit from ELGEMS. Please provide the acceptance criteria for the integrity check. Who will perform QA for in-coming NEC-8429 source to the site?

The correct statement should be: the integrity of the device received from the manufacturer (ELGEMS) is checked by qualified trained personnel during the MG ATC system installation (including the in-coming source NES-8429) according to the instructions described in the MG ATC Service Manual:

Note : attached updated MG ATC Service Manual - Rev 3 (page 3-3 was updated). Please, remove the Rev. 2 dated on July 27,1999 from the appendix B of the response file sent on 1/6/99 and insert this updated version Rev. 3, August 24,1999.

- a) **Verifying the line source Specifications (page 3-3 Hardware Installation). The purpose is to check and verify the source specifications (Model , radionuclide, activity) sent by the manufacturer to the site. Attached an example of the Performance Evaluation Source test report provided with the line source by the source manufacturer (DuPont Pharma).**
- b) **Radiation Leakage Test (Dry Wipe Test , page 3-6, Hardware Installation). The system is considered non-leaking if the radioactive content of the filter paper is less than 5nCi (185 Bq).**

c) **Shutter Function and Rod Motion Check (page 4-1, Attenuation Correction Check and System Calibration).**

The purpose is to ensure the functionality of the shutter mechanism and system motion control. The acceptance criteria for the integrity check is to pass all the tests listed in the table.

6. Who can handle, insert, and remove the source?: Only GE personnel or someone licensed by the NRC or an Agreement State? Please clarify pages 13 and 15 of 19 in the proposed certificate.

The correct statement should be: only qualified trained personnel or someone licensed by NRC or an Agreement State can handle, insert, and remove the source. Qualified field engineers should take part of the MG ATC Option course in the GE Training center.



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Gd-153 Transmission Line Source Performance Evaluation Sheet

Model Number: NES 8429

Lot Number: S8429P002-G0309

Radionuclide: Gd-153

Half-life: 242 days

Nominal Activity: 450 mCi (16.65 GBq)

Date: JAN-1998

Source Assay: 482 mCi (17.83 GBq) on 15-JAN-1998

SOURCE EMISSION UNIFORMITY

The gadolinium-153 line source emission of 100 keV photons was measured along its length in one centimeter segments. The uniformity was determined by taking the emission of the individual segment having the maximum deviation from the mean and dividing by the mean emission of all the segments. The uniformity of the source was determined to be $\pm 5\%$ of the mean emission.

PRINCIPAL PHOTON EMISSION ⁽¹⁾

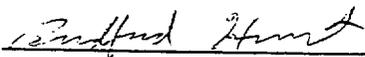
ENERGY (keV)	X-Ray (K)	X-Ray (K)	X-Ray (K)	Gamma-7	Gamma-8
	40.9	41.5	47	97.4	103.2
INTENSITY (%)	34.6	62.5	24.5	29.5	21.1

⁽¹⁾ A Handbook of Radioactivity Measurements Procedures, NCRP Report No. 58, Second Edition, (February 1985).

LEAK TEST CERTIFICATION

The subject source was leak tested for contamination and radioactivity leakage utilizing a wipe test technique prescribed by ANSI Standard N542-1977. Leakage/contamination of less than 5.0×10^{-4} microcurie was detected.

Date of Wipe Test: 12-JAN-1998

By: 
Bradford Hurst

Recommended Procedure:

This leak test procedure is recommended if the user does not already employ an approved procedure.

Wipe all external surfaces of the source or collimating holder with a piece of water moistened filter paper or other suitable "swab".

If the total activity smeared from the source is less than the previous smear test, and less than 5×10^{-4} microcurie, then the source is considered leak free. If the total activity measured is significantly more than the previous test value, then the source should be removed from service until the source leakage can be confirmed or other source of contamination found, (even though the detected quantity may be less than that specified on the user's license for reportable source leakage).

Record test results in a proper source log for future reference.