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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.

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We are in the process of reviewing you're 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 ± .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 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. 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	April1999	Procedures for fitting the ATC option to the Millennium MG system.	All	Sergio Steinfeld
	1 Provisional	May1999	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