

ENCLOSURE

1. NRC policy precludes the approval of a medical sealed source or device unless the applicant has submitted a copy of the pre-marketing approval [510(k)] certificate issued by FDA. Because the pre-marketing approval certificate is not submitted with the application, you should contact the FDA and obtain the appropriate approval certificate.
2. The source registration certificate identifies the source as Model Number is 34-5, whereas you state it as 34-5-1. Please provide the information on the differences between Models 34-5 and 34-5-1, if any.
3. We will list the maximum activity as 16.5 mCi on the registration certificate, derived from the nominal value of 15 mCi and the tolerance value of 10 percent of the nominal value. This is the maximum activity value that could be put into the device and the manufacturer must ensure that no device goes out exceeding that value. If the manufacturer cannot ensure that the maximum activity is not exceeded due to loading tolerances, you must address all issues related to maximum activity in the sealed source and device application and NRC will review it during the approval process. Please provide a copy of documentation indicating the assay date and the actual activity of the source along with tolerance, if any.
4. The application includes engineering drawings and radiation measurements in Appendix F that are marked as proprietary. Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.790. You must list all portions that you wish to be held proprietary, along with your reasons as to why the information is proprietary. Please provide two copies: (1) whole copy and (2) copy with proprietary information marked out and keep proprietary information to a minimum.
5. The Page 2 of 23 states that the septa collimator is either mounted in the camera or it is stored on the collimator cart in the restricted area, however, the Page 12 of 23 states that the septa collimator is permanently mounted to a camera gantry. Please clarify this discrepancy.
6. Please describe in detail the movement of the release handle from the source closed position to the open position and the lock mechanism for the source open position. Please address the issue that the lock mechanism could not fail (e.g., got stuck) in the open position.
7. In case of malfunction of LED position indicator, please provide other indications in addition to the LED for the source position. If not available, please provide redundant indications, e.g., mark the side wall of the push button "off" when the source rod is closed position and "on" when the source rod is being shifted.
8. Please provide the information about the interlock systems between the device and the operating room entrance door.

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9. Please provide engineering drawings with dimensions and tolerances in drawing No. ASM-000745-AA and Fig. A-4, .
10. Please indicate the actual activity, not the nominal activity, on the label drawing No. LBL-000452 and page E-4. Who will perform the actual activity measurement and what is the tolerance on that measurement? Why is the Model number missing in Label 5, whereas Label 4 shows it? The label indicates a term "Reference Date," such a term is not an accepted practice for sealed sources and devices. Please use conventional terms, such as assay date. The label indicates only the manufacturer in Israel. Please also show the address of the US distributor.
11. The radiation profiles with the shutter open at 5 and 30 cm are 15 and 3 mR/hr. However, using inverse square law with gamma factor of 3.3 R-cm²/hr-mCi and 15 mCi, they are estimated as 1980 and 55 mR/hr. Please clarify these discrepancies.
12. Please provide the prototype test result when subjected to conditions of normal use and likely accident conditions. A prototype product must be a complete representation of the final product that includes all safety features, shielding, safety markings (if appropriate), and accessory features or mounting that may have a detrimental effect to the safety and integrity of the product when subjected to normal or likely accident conditions such as being dropped during installation or bumped with hard objects (e.g., stretchers). Please provide the maximum installation height for this device in order to validate the drop test.
13. Please provide the external radiation profiles as well as radiation exposure for workers and other personnel when the patient, already injected with radiopharmaceuticals such as Tl-201 or Tc-99m, is handled by operating personnel during the procedure.
14. Please provide the radiation levels and exposure rates during other conditions of use, such as leak testing, calibration, etc.
15. Please provide any other services needed on the device, the collimator and gantry, including removal of the collimator from the gantry, which would result in doses other than the typical use dose scenarios provided.
16. Please provide the training and qualification requirements for the device users.
17. Please provide the description and engineering drawings for the gantry and other devices that are to be attached to the gantry.
18. The application stated that GE personnel checks the integrity of the device upon arrival in the US. Please provide the acceptance criteria for the integrity check. Who will perform quality assurance for the in-coming IPL 34-5 source to the site?
19. Please provide the details for the shipping container label and the organization that is responsible for ensuring the integrity of the shipping containers. Please provide the QA/QC for the shipping container.

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20. The Appendix H provides the source packaging information. Please clarify if this is the shipping container to be used for transporting the fresh sources to the users.
21. How is the thin source supported inside the shipping container? Please provide the details for the supporting mechanism.
22. Please provide (1) a copy of the current ISO 9001 certificate for Elgems, and (2) GE's QA/QC program as applied to receipt inspection, installation, and use in the USA.
23. Regarding quality systems audits at Elgems, please provide the specific frequencies for audit (e.g, quarterly, monthly, annually), who performs internal audits (GE Medical Systems or Elgems) and external audits. Does GE Medical Systems perform audit of Elgems? If so, please provide the annual frequency and actions to be performed. If not, please provide the rationale not to audit. Who performs audit and keeps the record of the audit results of the source manufacturer?
24. Please provide any special procedures for installation of the components such as mounting, interlocks, guards or barriers at the user's facility.
25. In the Operation Manual, please correct 5 η Ci to 5 nCi or 0.005 mCi (185 Bq) on page 5-4.
26. The Operation Manual and the Installation Manual should show the name and address of the US distributor.

June 5, 2000

Dr. James E. Beebe
GE Medical Systems
P.O. Box 414, NB-917
Milwaukee, WI 53201-0414

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR THE MODEL CoDe AC

Dear Dr. Beebe:

This letter is in response to your application dated March 17, 2000, requesting the evaluation and registration of Model CoDe AC attenuation corection device. We are in process of evaluating your request. In order to continue our evaluation, we need additional information attached in the Enclosure.

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application.

Please also note that NRC cannot issue a registration of your source until FDA has approved it for medical use in this country. Therefore, please send us a copy of Form 510(k) when you receive it.

If you have any questions, please contact me at (301) 415-5787 or Dr. John Jankovich at (301) 415-7904.

Sincerely,
/RA/

Seung J. Lee, Mechanical Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

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* See previous concurrence

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June 5, 2000

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Milwaukee, WI 53201-0414

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Enclosure: As stated