



UNITED STATES
 NUCLEAR REGULATORY COMMISSION
 WASHINGTON, D.C. 20555-0001

DATE: 7/11/89

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
 DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY

FAX TRANSMITTAL

	TO	LOCATION
1.	<u>Dr. James Be Be</u>	_____
	FAX # <u>(414) 548-5197</u>	VERIFICATION () _____
2.	_____	_____
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	FAX # () _____	VERIFICATION () _____

COMMENTS:

Please respond within 30 days.

COVER SHEET PLUS 2 PAGES

FROM: Seung Lee

PHONE: (301) 415-5787

FAX: (301) 415-5369

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 effects of two source "L" deployment and Tc-99m transmission on the bonding capability of the epoxy were taken into consideration.
 - 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.
 - c. Please clarify 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 specified as $\pm .010$ and $\pm .005$ for .xx and .xxx, respectively. What tolerance is used for ATC Rod Unit?
2. Please provide the external radiation profiles as well as radiation exposure for workers and other personnel when the patient, already injected either TI-201 or Tc-99m, is inside the radiation beams.
3. Please provide the radiation levels and exposure rates during other conditions of use, such as leak testing, calibration, etc.
4. Please provide the training requirements for field engineers to remove, replace, install, and repair of the Rod Units.
5. Please provide the requirements and qualifications for the device users.
6. Please provide the corrected warning statement in Service Manual page 5-4.

Please provide the requested information within thirty (30) days. If we do not receive the requested information within thirty (30) 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. If you have any questions, please contact me at (301) 415-5787.

TRANSMISSION REPORT

01.01.2040 00:00

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DATE TIME	DURATION	REMOTE ID	MODE	PAGES	RESULT
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