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JUL 18 1985

Good Samaritan Medical Center
Lutheran Campus
ATTN: Mr. John Schwartz
President
2000 W. Kilburn Avenue
Milwaukee, WI 53233

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License No. 49-00988-04

Gentlemen:

We have reviewed your letters dated June 18, 1985 and July 3, 1985 requesting an amendment to your nuclear medicine license and find that we will need additional information as follows:

1. With the addition of Dr. Richards to your license it would be possible for us to remove the "for storage only" restriction for Group VI material from your license. However, the letters and application currently referenced in your license contain no safe handling procedures, nursing instructions or source accountability system for Group VI licensed material. If it is your intent to be authorized for all of the material listed in 10 CFR Part 35, Schedule 35.100 (f) (enclosed), you will need to submit this information in accordance with Appendix L of Regulatory Guide 10.8 (enclosed). If, on the other hand, it is your intent to use only your strontium-90 eye applicator, you need only submit the information requested in Items 3, 4 and 6 of the enclosed strontium-90 ophthalmic applicator guide.
2. With regard to the addition of Drs. Veluvolu and Whalen we note that they had personal participation in 15,000 and 10,000 generator elutions, respectively (ref. Supplement B, Form 313M) as well as an equal number of kit preparations. Please note that Appendix A, Section 2.b. of Regulatory Guide 10.8 request evidence of personal participation in a minimum of five procedures to elute Tc-99m and preparation of radiopharmaceuticals from Group III reagent kits. The numbers you have provided are in excessive for the time frames involved. (They imply that each physician eluted a generator approximately 100 times per week.) Please review these entries with the physicians involved and revise them accordingly.

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We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 79286.

Sincerely,

Original Signed By
William J. Adam, Ph.D.
Materials Licensing Section

Enclosures:

1. 10 CFR Part 35
2. Regulatory Guide 10.8
3. Information to be Submitted for
Strontium-90 Ophthalmic Applicator

RIII

wja
Adam/cm
07/15/85