MAY 3 1 1985

License No. 29-03038-01
Docket No. 030-02464
Control No. 103696

The Hospital Center at Orange
ATTN: Anna Austin
Chief Technologist
188 South Essex Avenue
Orange, New Jersey 07051

Gentlemen:

This is in reference to your request in a letter dated April 12, 1985, to renew License No. 29-03038-01. In order to continue our review, we need the following additional information:

1. In Item 6a of your application, Radioactive Material for Medical Use, you have requested authorization for the same materials for which you were previously licensed. However, none of the individual users you have listed in Item 4. of your application are authorized to use Group VI materials. Your present license authorizes Thomas Borok, M.D. for Group VI materials, but his name was not included as an individual user. Please clarify.

2. If you do wish to have continued authorization for Group VI materials, then procedures for the therapeutic use of sealed sources must be provided. In this case please confirm that the procedures in Appendix L of Regulatory Guide 10.8 will be followed. Alternatively, you may submit equivalent procedures.

3. Please specify whether Tc-99m generators will be used. If you do plan to use generators, please describe your waste disposal procedures for the generators. Appendix J of Regulatory Guide 10.8 provides an approved waste disposal procedure for generators.

4. Also, if you plan to use generators, then you should have available in your department a high-level survey meter capable of reading up to one Roentgen per hour in order to measure radiation dose rates that may exist in the vicinity of Tc-99m generators, etc. Please indicate the manufacturer's name, model number, and highest level range of the instrument in your laboratory that will fulfill this need.

5. Item 10. of your application, Calibration of Instruments, indicates that calibration procedures for the dose calibrator will be the same as used

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previously, i.e. the procedures specified in Appendix D of Regulatory Guide 10.8. However, during a recent inspection of your program, it was learned that you are using a Cali-Check method of performing the linearity test, a test procedure which is not included in Appendix D. Please specify your dose calibrator linearity test procedures and the frequency with which they will be performed. Please confirm that prior to your sole use of the Cali-Check method it will be validated by comparing the results with the linearity test procedure specified in Appendix D of Regulatory Guide 10.8.

6. Your application did not include an ALARA Program. Please submit a copy of your ALARA Program. If you choose to adopt the model ALARA Program contained in Appendix O of Regulatory Guide 10.8 (enclosed) simply fill in the blanks on the first and last pages of the program have a representative of your management sign the program on the last page and submit it with your response to this letter.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I office and refer to Mail Control No. 103696.

Sincerely,

Original Signed By:
Edwin A. Wurtz

Edwin A. Wurtz, Ph.D
Nuclear Materials Safety Section B
Division of Radiation Safety
and Safeguards

Enclosure: Regulatory Guide 10.8

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