SEP 2 1982

Docket No. 030-13111 License No. 37-11438-02
Control No. 11875

Franklin Hospital
ATTN: John A. Stanton
Administrator
Spruce Street
Franklin, Pennsylvania 16323

Gentlemen:

This is in reference to your application dated June 25, 1982, to renew License No. 37-11438-02. In order to continue our review, we need the following additional information:

1. A proposed rule change requires that a hospital's Medical Isotopes Committee include a representative of the nursing staff. It is expected that this change will be made in the near future. Please submit the name and title of the individual who will fill this need.

2. Please identify the reference standards that you will use to perform calibration procedures for your dose calibrator. In order to follow the procedures outlined in Appendix D, Section 2, you will need reference standards of at least high and low energy (e.g., cesium-137 and cobalt-57). In addition, it is recommended that you use a reference standard of intermediate energy (e.g., barium-133).

   The source activity levels should approximate those levels normally encountered in clinical use (e.g., cobalt-57, one millicurie or more; cesium-137, one hundred microcuries or more, etc.). In identifying the sources that you will use, state the nuclide activity and calibration accuracy.

3. Your dose calibrator linearity tests must include the maximum activity that is assayed in the dose calibrator (i.e., the first elution from a new Tc-99m generator). Please confirm.

4. Radiation workers (technologists, etc.) must receive instruction as specified in 10 CFR 19.12 (enclosed). Note that many of these items pertain to circumstances at your particular institution; therefore, you may not assume that this instruction has been adequately covered by period occupational training, board certification, etc. Please outline and submit your program for providing the necessary instruction. Confirm that this instruction will be given both initially and annually thereafter on a refresher basis.

5. You are requesting authorization to use Groups IV and V radiopharmaceuticals. Please submit the precautionary measures and the bioassay procedures that you will follow when using iodine-131 in liquid form, or confirm that iodine-131 will only be received and administered as capsules. Regulatory Guide 8.20, which covers bioassay procedures, is enclosed.

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6. You have requested authorization for medical use of radioactive material listed in 10 CFR 35.100, Schedule A, Group VI.

   a. You are not currently authorized for Group VI; and, therefore, none of your physicians are currently authorized. A physician to be authorized for Group VI must be certified by the American Board of Therapeutic Radiology (or equivalent certification), or must meet the training and experience requirements described in Section 5.C of Appendix A in Regulatory Guide 10.8 enclosed. Please submit.

Withdrawn

   b. You have committed yourself to the radiation safety procedures described in Appendix L of Regulatory Guide 10.8. In addition, you must:

      1) Describe your method for determining the radiation dose to the extremities of personnel handling sealed sources.

      2) Describe the equipment and shielding available for storage and for transporting the sources from storage sites to the place of use.

      3) Describe your method for maintaining source accountability at all times. This should include a description of your sign-in and sign-out procedures, periodic inventory, and your method for determining that all sources are accounted for and returned to storage following treatment.

7. We note that you are currently authorized to possess americium-241 sealed sources, each containing up to 50 nanocuries. You did not include these in your application. Is this an oversight, or do you no longer possess these sources?

OK

We will continue our review of your application upon receipt of this information. Please reply in duplicate and refer to Control No. 11875.

Sincerely,

Original Signed By:
Phillip C. Jerman

Phillip C. Jerman
Materials Program Section No. 2
Division of Engineering and
Technical Programs

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Enclosures:
1. 10 CFR 19
2. Regulatory Guide 8.20
3. Regulatory Guide 10.8

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SURNAME	Jaynes	Glenn					
DATE	8/31/82	8/31/82					