Affiliated with Jefferson Medical College

FRANKLIN HOSPITAL

September 16, 1982

Nuclear Regulatory Commission
Region 1
631 Park Avenue
King of Prussia, PA 19406

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

Dear Mr. Jerman:

RE: Docket #030-13111
Control 11875

Dear Mr. Jerman:

Enclosed are the responses to your request for additional information for renewal of License #37-11438-02 and all of its amendments.

Sincerely yours,

Charles E. Mason, M.D.
Radiologist

CEM/nt

Enclosure

ML10

"OFFICIAL RECORD COPY"

11875
SEP 21 1982

RESPONSES TO LETTER OF SEPTEMBER 2, 1982

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.

   RESPONSE: Judy Lowery, R.N.
   Nursing Supervisor

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 indeterminate 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 of more, etc.). In identifying the sources that you will use, state the nuclide activity and calibration accuracy.

   RESPONSE: Reference standards used to perform calibration procedures for the dose calibrator.

   a) Cesium-137 Mallinkrodt Code: 054, Lot 2FA
      June 1, 1972 1.0 millicuries.
      January 19, 1982 0.802 millicuries

   b) Cobalt 57 Gamma Reference Source New England Nuclear
      NES-206SER. 2060482B-13
      Activity 4.8 millicuries of 4/26/82.
      Epoxy sealed in 20 millileter vial.

   c) We posses no barium-133 reference standard as it has not been a requirement.

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.

   RESPONE: This confirms that the dose calibrator linearity tests include maximum activity that is assayed in the dose calibrator which includes the first elution from a new technetium 99m generator.

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.

   RESPONSE: Radiation workers (technologists, etc...) will receive instruction as specified in 10 CFR 19.12. It is confirmed 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.

   RESPONSE: It is confirmed that I-131 will only be received and administered in the capsule form. It will not be received or administered in liquid form.

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

   RESPONSE: a) Please delete the request for authorization for medical use of radioactive material listed in Group 6.

   b) Please delete the request for authorization for medical use of radioactive material listed in Group 6.

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?

   RESPONSE: The Americium-241 source is covered under Amendment Number 4 of License #3711438-02, Docket or Reference #030-13111. This was received July 9, 1982. The request for renewal of the current license was to include all the amendments appended to that license which would include this amendment #4 for Americium. It was received after the license renewal application was sent to the NRC. In any case, the amendment does exist on the current license, and I would like this amendment to be renewed along with the license and all of the other amendments.