Yale New Haven
1826 Hospital
20 York Street, New Haven, CT 06504

MS 18
P5

July 1, 1985

Jenny M. Johansen, M.S.
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards
United States Nuclear Regulatory Commission
Region 1
631 Park Ave
King of Prussia, PA 19406

Dear Mrs. Johanson:

We received a letter from you regarding our December 13, 1984, application to renew license #06-00819-03. In your letter you asked for additional information through a series of eight or nine questions. Please find attached for your review, the answers to those questions. I noted that in question #9 you stated that the application should have been signed by the Hospital Administrator and not Dr. Eugene A. Cornelius. You also required a letter from the Hospital Administrator indicating that he or she had reviewed the application and concurs with the statements and representations contained therein. We certainly have reviewed the application and concur with its contents, and will be sure that the Hospital Administrator will sign all future correspondence, requests for amendment, and renewals.

We appreciate the thoroughness of your reviews and look forward to working with you in the future.

Sincerely,

Daniel J. McIntyre
Associate Administrator

cc: Jim Joyner
John Glenn

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1. The address given in our license renewal application (20 York Street) is Yale New Haven Hospital's correct mailing address. Our broad licensed activities differ from those of Yale University's licensed activities. Regulations however, are similar to allow reasonable continuity for the researchers. All activities covered by the Hospital's license are initiated and completed on Hospital property.

2. A quorum to conduct a meeting consists of 50% or more of the membership. Routine matters are handled in these meetings discussed not only with the members present at the meeting, but a letter or telephone call from the Chairman is made to all members, informing them of the issues. Research protocols are consistantly circulated to committee members by mail. Naturally, appropriate consideration is given to the field of expertise of each committee member when research protocols are distributed. For example, a member from Administration would not be expected to evaluate a research protocol from the point of view of the radiation exposure, clinical benefit ratio. If warranted, outside opinions, here or elsewhere, may be obtained.

3. The Radiation Safety Officer does have the authority to immediately terminate projects found to be a threat to health, safety or property. The Radiation Safety Officer does have an immediate and direct line of communication with the Hospital's Administration for reporting items of noncompliance, with NRC rules, regulations, and license conditions.

4. All individuals working in areas where radiation and/or radioactive materials are used are trained upon hiring and will attend a reinforcement inservice program or session annually.

5. Radioactive materials are being received, used, and disposed of under the Hospital's license. In subitem 4, page 13-1, limited human research is being funded by various grants. These grant resources are under the control of Yale University. To ensure compliance with both Hospital and University regulations, the purchasing requisitions must be approved by qualified personnel in both organizations.

6. Radioactive waste generated by the Hospital will be handled by either holding the waste until it reaches background levels, or sending it to a Vendor who handles radioactive waste. Additionally, aqueous radioactive waste is disposed via the sewer according to NRC rules and regulations.

7. The calculations on pages 21-3, 21-4, 21-5, and 21-6 are in microcuries per millimeter not curies per milliliter.

8a. Selenium-75 will not be used as a replacement source for the iridium-192 in the Gamma Med II Remote Afterloader. Please disregard this in our application.

8b. Since some of our researchers have dual positions at Yale New Haven Hospital and at Yale University School of Medicine, it is best to keep regulations for the Hospital and the University as similar as possible.

8c. No reporting is required by the NRC on each case of nonroutine human use of radioisotopes. It is also noted that the Food and Drug Administration has certain controls over this aspect.

8d. The FDA will be contacted regarding their requirement for IND's for clinical diagnostic evaluation of radiopharmaceuticals. It is also noted that the current guide for Medicial Licensing is Regulatory Guide 10.8 (Rev. 1) October, 1980.

8e. Our program will cover any laboratory research which involves information pertaining to new radiopharmaceuticals for human research of evaluation.

In our license renewal application it was stated that the linearity of our dose calibrators will follow that which is stated in the Regulatory Guide 10.8 (Rev.1) October, 1980. In addition to this, we want to be able to use the device called the Calicheck from Calcorp, Inc., (Enclosed some information about this device).