file

JUL 30 1985

Methodist Hospital
ATTN: Robert Anger
Radiation Safety Officer
1604 North Capitol Avenue
Indianapolis, IN 46206

SUBJECT: REQUEST FOR RENEWAL OF LICENSE NUMBER 13-02063-01 DATED MAY 30, 1984 AND OUR REQUEST FOR ADDITIONAL INFORMATION BY PHONE ON MAY 16, 1985

Gentlemen:

We requested in the above mentioned telephone conversation between Mr. R. Anger and Ms. Evelyn Matson of our office that you respond to us with the following additional information:

1. Please identify the scope of your program and the types of use of byproduct material the Radiation Safety Committee (RSC) will review and approve. For example, you program may consist of:

   a. routine medical diagnosis and therapy;

   b. human research;

   c. non-human research;

   d. using approved drugs for unapproved procedures in accordance with the provisions of 10 CFR 35.14(b)(6) for medical diagnosis or therapy;

   e. Investigational New Drug Applications;

   f. using approved drugs for unapproved procedures which do not meet the provisions of 10 CFR 35.14(b)(6) for medical diagnosis or therapy; and/or

   g. using unapproved drugs for medical diagnosis or therapy.

2. Submit a description of the RSC including the following:

   a. duties;

   b. meeting frequency;

   c. list of members by discipline;

   d. list of core members by name (example: chairman, RSO, physicist, etc.);

   e. criteria for approving users for each type of use as specified in Item 1, a through g above; and

   f. criteria for approving facilities where byproduct material will be used.

3. Indicate that an active RDRC will review all procedures for human research.

4. Submit radiation safety procedures that will be followed for using therapeutic radiopharmaceuticals. Procedures should be equivalent to Regulatory Guide 10.8, Appendix K.

5. Submit the criteria the RSC will use for approving the use of millicurie quantities of high energy beta emitters and radioiodines. Procedures should include use of low density shielding material, extremity monitoring, conducting surveys after each use, use in hoods, etc.

6. Please submit an ALARA program for your institution. You may adopt Regulatory Guide 10.8, Appendix O or submit an equivalent program.

7. Clarify that the RSC will be reviewing and approving facilities for radioisotope use and that the only facilities that will be "tied down" in the license are special use areas (e.g., xenon use areas, sealed source brachytherapy storage, animal housing, iodination locations) and all other areas are subject to change by approval of RSC.

A check of our files indicate that we have not received a response from you to date. You are hereby notified that you have 30 days in which to submit a response to this notice.

Upon failure to file an answer within the specified time, we will considered your request abandoned and will void this action. This is without prejudice to resubmission of the application.

Please respond in duplicate and refer to Control Number 76894.

Sincerely,

Original Signed By
Bruce S. Mallett, Ph.D., Chief
Materials Licensing Section

RIII

Mallett/cm
07/25/85