AUG 11 1993

License No. 08-01738-02
Docket No. 030-01317
Control No. 117725

Department of The Army
Walter Reed Army Medical Center
ATTN: Major General Ronald R. Blanck
Commanding Officer
Washington, D.C. 20307-5001

Dear Major General Blanck:

This is in reference to your application dated January 21, 1993 to renew License No. 08-01738-02. In order to continue our review, we need the following additional information:

1. Please submit the Radiation Safety Committee's (RSC) procedures and criteria for making safe evaluations of proposed uses of radioactive material that will demonstrate the Committee's process for obtaining permission to use radionuclides. A typical "application for authorization" for human and non-human use submitted to the Committee for review should as a minimum take into account the radionuclides, physical/chemical form, and maximum activities requested by the applicant, the applicant's training and experience with the nuclides requested, the training and experience of personnel working for the applicant, the use of the requested nuclide, the applicant's facilities and equipment, and any specific hazard in the operations with the radionuclides. You should submit an example of your authorized user application and approval forms.

2. Please review the enclosed Information Notice 90-09. You may wish to develop an Interim Waste Storage Plan at this time. If you do not wish to develop an Interim Waste Storage Plan, a condition will continue to be placed on your license that allows storage of LLW for a rolling two year period. Submittal of an Interim Waste Storage Plan amendment in accordance with Information Notice 90-09 would be required to remove this condition from your license.

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3. In your request for case by case exemption from the requirements in Subpart J please confirm that exceptions are only made for unique/non-routine clinical studies that are within the physician's field of expertise and exceptions are not used to circumvent the Part 35, Subpart J requirements for routine studies. Please also submit the minimum training and experience criteria that you will use for these exceptions.

4. Please describe in greater detail the frequency and elements of your radiation safety office audits of the performance of individual authorized investigators that will assure that your program is operating in accordance with your procedures.

5. Please describe any special use facilities and equipment such as iodination facilities $>$ 10 millicuries, large use labs $>$ 100 millicuries or compactors.

6. What records will you maintain of training and testing of personnel? Please also confirm that your training program will include instructions on emergency procedures and include provisions for periodic exercises.

7. Regarding your use of animals in research:

   a. Please describe the animals' housing facilities or the criteria that the RSC will follow in approving animal housing facilities.

   b. Please submit a copy of instructions provided to animal caretakers for handling of animals, animal wastes and carcasses.

   c. Please submit a copy of instructions on cleaning and decontamination of animal cages.

   d. Please submit your procedures for ensuring that animal rooms will be locked or otherwise secured unless attended by authorized users of byproduct material.

8. Please specify your trigger or action levels for removable contamination and radiation levels when performing radiation surveys.

9. With regard to your request for authorization to decay in storage materials with half-lives of less than 90 days for only 5 half-lives rather than 10 half-lives please provide the following additional information:

   a. For all byproduct materials with half-lives of greater than or equal to 65 days, you must specifically identify the isotopes desired and describe the instrumentation and monitoring procedures that will be used to determine that the waste is free of radioactive contamination at the end of the storage period.

b. For specific byproduct materials to be held only 5 half-lives, identify these separately and indicate how you will assure that the waste will contain less than the quantity of radioactive material specified in 10 CFR 20, Appendix C per waste container when placed in storage. Use the 1/R rule for multiple isotopes.

10. In Item 3 of your application you have added the Gillette building. Please provide a description of what byproduct materials uses and quantities will be used in this facility. You should indicate approximately how many laboratories you plan to establish and their general location.

11. Please note that M.1 and M.2 of Regulatory Guide 10.8, Revision 2 are missing some required information. M.1 should include the expiration date and M.2 should include expiration date and lot number.

12. Your described area radiation and contamination surveys may not be adequate for your non-medical use program. Please provide greater detail on your minimum requirements for surveys in the rest of your broad scope program. You should develop a plan for minimum survey frequencies for laboratories based on categories of risk as determined by types, quantities, and forms of byproduct material that will be handled. Please also include your action limits for survey results.

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. 117725. If you have any technical questions regarding this deficiency letter please call me at (215) 337-5303.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Original Signed By:
Thomas K. Thompson

Thomas K. Thompson
Senior Health Physicist
Nuclear Materials Safety Branch
Division of Radiation Safety
and Safeguards

Enclosure:
Information Notice 90-09

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