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MAR 15 1985

Marshfield Clinic
ATTN: Mr. Fredrick J. Wenzel
Executive Director
1000 North Oak Avenue
Marshfield, WI 54449

License No. 48-10966-03

Gentlemen:

We have reviewed your application dated November 15, 1983 requesting renewal of NRC License Number 48-10966-03 and find that we will need additional information as follows:

1. If your institution conducts basic research studies involving human subjects to determine if a drug may have eventual therapeutic or diagnostic application, you must conduct these studies under either a physician or institution - sponsered IND (Notice of Claimed Investigational Exemption for a New Drug) from the FDA or have the research protocal approved by an FDA-approved RDRC (Radioactive Drug Research Committee). If your chose the latter, please indicate the name of the RDRC and provide some evidence of its FDA approval.

2. Please review Items 6.a. and 6.b. of the enclosed Appendix Q to Regulatory Guide 10.8. Note that it asks you to specify both the 10 CFR Part 35 Groups that your institution will use as well as material with atomic numbers 3 through 83. Both catagories of material will be listed on your license to insure a clear separation between your routine diagnostic and therapeutic procedures and your research studies. You should resubmit those items you desire to be listed under Items 6., 7., 8. and 9. of your license, specifying possession limits for Groups III and VI. You may wish to adjust the possession limits for the non-Part 35 group materials you have already listed accordingly.

3. Your dose calibrator calibration procedures do not appear to include a test for energy accuracy using low, medium and high energy sources. Please review the enclosed Regulatory Guide 10.8, Appendix D, Section 2.F. and submit equivalent procedures.

4. Please supplement your receipt procedures to include precautions to be followed in the event of receipt of byproduct materia' packages during off-duty hours. As a minimum, these procedures should include:

   a. designation of a central receiving/storage point

   b. designation of responsible individual(s)

c. precautions to be followed in the event of receipt of a damanged byproduct material package, including:

(i) notification of the R.P.O.

(ii) retaining delivery personnel until it can be determined that neither they nor their delivery vechicle is contaminated

(iii) proper handling procedures for packages suspected of being contaminated

5. Item 14 of your application appears to exempt certain packages containing licensed material from safe opening procedures. There are no exemptions from safe opening procedures in 10 CFR 20.205. Basically, 10 CFR 20.205 is divided into four parts:

a. Paragraph (b) refers to monitoring for surface contamination upon receipt of packages containing licensed material. This contains the exemption quoted in Item 14 of your application.

b. Paragraph (d) refers to procedures for safely opening packages containing licensed material. There are no exemptions in Paragraph (d).

Appendix F of Regulatory Guide 10.8 contains a method that is acceptable to the NRC staff for implementing the regulation in 10 CFR 20.205(d), which applies to all packages containing licensed material. You cannot use the exemptions in 10 CFR 20.205(b), which apply to receiving packages, as a substitute for the procedures in Appendix F which apply to opening packages.

6. Please describe what procedures are used by the Radiation Safety Office to insure that users authorized by the Radiation Safety Committee are conducting their activities in accordance with the conditions of their authorization. Your description should include, but not be limited to:

a. the frequency of the audits-renewals

b. areas covered during such audits

c. actions taken when problems are identified.

7. Please confirm that individuals handling sealed sources for therapy will be required to wear extremity monitoring.

8. You should measure the airflow rates in the ventilation systems for xenon-133 at least semiannually to determine that system performance meets the specifications stated in your application. Please confirm.

9. If transportation of byproduct material occurs between those places of use you have listed in Item 1.a. of your application, please submit a copy of your procedures for safely transporting this material. These procedures should include, but not be limited to:

   a. methods of insuring compliance with 10 CFR Part 71 (i.e., packaging, labeling, etc.)

   b. emergency procedures to be followed in the event of an accident

   c. methods for ensuring security of the material if unattended.

10. If radioactive materials are to be used in animals, please submit:

   a. A description of the animals' housing facilities.

   b. A copy of the instructions provided to animal caretakers for handling of animals, animal waste, carcasses, and cleaning and decontamination of animal cages.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 16248.

Sincerely,

Original Signed By
William J. Adam, Ph.D.
Materials Licensing Section

Enclosures:
1. Regulatory Guide 10.8
2. Appendix Q

RIII
WJA
Adam/cm
03/11/85