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JUN 28 1985

Wm. S. Middleton Memorial Veterans Hospital
ATTN: R.E. Poleyn, M.D., Chairman
Radiation Safety Committee
2500 Overlook Terrace
Madison, WI 53705

License No. 48-01183-01
Reference No. 607/002

Gentlemen:

We have reviewed your application dated August 10, 1983 requesting renewal of your Type A Broadscope license and find that we will need additional information as follows:

1. 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 categories of mateiral will be listed on your lciense to insure a clear separation between your routine diagnostic and therapeutic procedures and your research studies. You should resubmit Items 6.a. and 6.b. of your application specifying a possession limit for Group III. You may wish to adjust the possession limits for the non-Part 35 group materials you have already listed accordingly.

2. Please confirm that the Radiation Safety Officer shall have the authority to immediately halt any activity he judges to be a threat to health, safety, property, the environment or a violation of the regulations or the conditions of your license.

3. Please describe what criteria the Radiation Safety Committee will use to review the folliwing:

   a. Facilities for byproduct material use (a copy of typical criteria used for such a review is enclosed).

   b. Potential users for non-human use. As a minimum, the criteria listed in 10 CFR 33.15(b), of Part 33 would apply.

   c. Potential users for human-use. As a minimum, the criteria in Appendix A of Regulatory Guide 10.8 (October, 1980) would apply (copy enclosed).

4. If your institution conducts basic research studies involving human subjects to determine if a drug may have eventual therapeutic or diagnositc 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 protocol approved by an FDA-approved RDRC (Radioactive Drug Research Committee). If you choose the latter, please indicate the name of the RDRC and provide some evidence of its FDA approval.

5. Please describe what procedures are used by the Radiation Sfety 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. who will conduct such audits or renewals

   c. actions taken when problems are identified.

6. Please confirm that the linearity test performed on your dose calibrator will be initiated with the maximum activity you anticipate assaying in that instrument.

7. Please revise your package opening procedures to include a lower action level for surface contamination. The level you have referenced (220,000 dpm/100cm$^2$) is excessive for your type of institution and conflicts with 10 CFR 20.205.

8. In order for us to continue your authorization for incineration of radioactive material, we will require additional information. Please specifically state the isotopes and the maximum amount of each isotope you wish to incinerate per burn and respond to items 1, 3, 4, 6 and 7 of the enclosed guidelines for incineration.

9. You may wish to restate, or at least compare, your action level for bioassays (25% of MPBB) to MPC-hours. This would clarify at what point you would need to take corrective action and maintain compliance with Part 20.

10. It appears that you intend to restrict radioiodine therapy patients to only two rooms. If this is not the case, please confirm that radioiodine therapy patients will be confined to private rooms only.

11. Please resubmit the diagram for your xenon use and storage areas. Both exhaust and supply vents should be specified as well as their respective flow rates. The information submitted should be sufficient to demonstrate that these areas are under negative pressure. If these areas are not under negative pressure, you should describe what engineering controls you will employ to achieve such a result.

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 15688.

Sincerely,

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

Enclosures:
1. Criteria for Facilities
2. Appendix Q
3. 10 CFR Parts 33 and 35
4. Regulatory Guide 10.8
5. Incineration Guidelines

RIII
WJA
Adam/cm
06/26/85