"OFFICIAL RECORD COPY"

NOV 20 1987

Veterans Administration Medical Center
ATTN: Dr. R. B. Wimmer, Director
800 Zorn Avenue
Louisville, KY 40202

Gentlemen:

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION CONCERNING A MATERIAL LICENSE APPLICATION (REFERENCE: 251794, 030-01747)

This refers to your letter dated September 14, 1987, for renewal of License Number 16-03121-02.

Effective April 1, 1987, NRC revised 10 CFR Part 35 applicable to medical use of byproduct material. We have also revised Reg. Guide 10.8 (August 1985). In order that your program be in conformance with the new 10 CFR 35 and Reg. Guide 10.8 (August 1987), we are enclosing them for your use. In responding to this letter, please use the enclosed guide as a reference. The model procedures (Appendices to Reg. Guide 10.8) are acceptable to the NRC for licensing purposes and may be referenced in lieu of submitting alternate procedures.

In order to continue the review of your renewal request, we will need the following information and clarifications:

1. Your attachment for Item 5 and Item 6 (Table 1) states that the possession limit for any radionuclide listed in Section 33.100, Schedule A, is as needed and that the use of this material is for medical purposes. This is inconsistent with 10 CFR 33.11(b) and 10 CFR 33.17(a)(4). Please specify that this material will not be administered to human subjects and that you will comply with the possession limits stated in 10 CFR 33.11(b). Also, you were previously licensed for this material for research and development as defined in 10 CFR 30. Technically, this does not include routine in vitro clinical or laboratory testing as described in 10 CFR 31.11. Specify if you would like it to cover these routine uses also.

   Also, your attachment for Item 5 and 6 (Table 1) only lists an eye applicator for therapeutic use under in 35.400. Do you want to be licensed only for the eye applicator or for all sources in 35.400? If you choose the latter, we will need additional procedures as discussed later in this letter.

2. Submit either the training and experience of individuals you wish to be named as authorized users, or submit the criteria you use to evaluate the training and experience of your authorized users. You should have separate criteria for human and non-human uses.

3. For Item 9 (Facilities and Equipment), submit the following additional information and clarifications:

a. Describe your program for assuring adequate face velocity at the entrance to your fume hood(s) where radioactive materials are used and/or stored. Such measurements should be made quarterly by using a properly calibrated thermoanemometer or velometer to determine whether airflow has been reduced to unacceptable levels by filter loading or malfunctions. The minimum average face velocity with the sash in the operating position should be 100 ft/min. as determined from at least five difference measurement points. Records should be kept of these measurements and any corrective actions.

b. Submit your procedures for calibrating survey instruments, or reference Appendix B of Reg. Guide 10.8, Rev. 2 (August 1987). Your procedures submitted with your application dated May 15, 1979, do not satisfy the requirements of 10 CFR 35.51.

c. Submit your current procedures for calibrating dose calibrators, or reference Appendix C of Reg. Guide 10.8, Rev. 2 (August 1987). Your application dated May 15, 1979, references Section 2 of Appendix D to Reg. Guide 10.8 (January 1979) which is no longer used or available.

d. Describe your personnel monitoring program, or reference Appendix D of Reg. Guide 10.8, Rev. 2 (August 1987). Also, submit your bioassay program for individuals handling millicurie quantities of I-125 or I-131. Enclosed is Reg. Guide 8.20 for your reference.

4. For Item 10 (Radiation Safety Program) revise your earlier submissions to include the following information or reference the appropriate Appendices to Reg. Guide 10.8, Rev. 2 (August 1987):

a. Describe your Radiation Safety Committee. (The membership composition submitted with your May 15, 1979, application does not satisfy the requirements of 10 CFR 35.22). Also, describe your Radiation Safety Committee Charter and the Radiation Safety Officer's Delegation of Authority.

b. The ALARA Program submitted was unsigned. Please submit a signed copy.

c. Submit a copy of your leak test procedures, or reference Appendix H. Your procedures were not previously submitted.

d. Your "Procedures and Precautions for Use of Radioactive Materials...." should be improved to include the use of syringe shields, labeling doses and vials, dose measurements prior to administering the dose to the patient, etc., or reference Appendix I.

e. Submit your procedures for handling spills, or reference Appendix J.

f. Submit your procedures for safely opening packages, or reference Appendix L.

NOV 20 1987

g. Submit your procedures for measuring and recording Mo99 concentrations in Tc99m doses, or reference Appendix M.3.

h. If you want to be licensed for implant sources, submit your procedures for inventorying them, or reference Appendix M.4.

i. The area survey procedures submitted with application dated May 15, 1979, use a contamination limit of 100 cpm per 100 cm^2 for wipe tests. Be aware that 10 CFR 35.70 requires records of removable contamination be expressed in disintegrations per minute per 100 cm^2 and that you must be able to detect at least 2000 dpm per 100 cm^2. Your procedures should be revised, or reference Appendix N.

j. Submit your procedures for radiation safety during radiopharmaceutical therapy, or reference Appendix P.

k. If you apply for implant sources in 35.400, submit your radiation safety procedures for implant therapy, or reference Appendix Q.

5. Submit your procedures for handling waste, or reference Appendix R. Your application dated May 15, 1979, listed methods of disposal but did not give procedures.

Upon receipt of pertinent documentation, we shall be pleased to continue our review to renew your license. During the review process, your expiring license shall remain in force until our review is complete.

If you have any questions about our requirements, please call me at (404) 331-2675.

When replying, please refer to Mail Control No. 251794 and provide two copies of all information.

Sincerely,

Carol A. Connell

Carol A. Connell
Radiation Specialist
Nuclear Materials Safety Section

Enclosures:
1. 10 CFR Part 35 (Revised)
2. Reg. Guide 10.8, Rev. 2, (August 1987)
3. Reg. Guide 8.20

cc: James W. Fletcher, M.D.
Director, NMS (115)
VA Central Office
810 Vermont Avenue N.W.
Washington, DC 20420

RII CAC
CConnell:tj
11/20/87

RII
JPotter
11/20/87