

12 SEP 1984

License No. 37-16245-01
Docket No. 030-10656
Control No. 02444

Central Medical Center and Hospital
ATTN: Thomas M. Gallagher
1200 Centre Avenue
Pittsburgh, PA 15219

Gentlemen:

This is in reference to your application dated May 21, 1984, to renew License Number 37-16245-01. In order to continue our review, we need the following additional information:

1. Your application indicates you request material for in vitro studies, but it does not state a possession limit in millicuries for each radionuclide listed in Section 31.11 of 10 CFR 31. 10 CFR 35 Section 35.14(c) states any licensee who is licensed pursuant to paragraph (a) of this section for one or more of the medical use groups in 35.100 also is authorized to use byproduct material under the general license in 31.11 (enclosed) of this chapter for the specified in vitro uses with up to 200 microcuries of each isotope without filing Form NRC-483 as required by 31.11(b) (enclosed). Please clarify which method of authorization applies to your program. Please indicate if your possession limits will exceed those in 31.11.
 2. In accordance with letter dated June 11, 1980, Condition 12. was amended to read:
 12. Licensed material shall be used by, or under the supervision of Morris Z. Gardner, M.D., Vallabhoneni S. Babu, M.D., or Richard S. Gordon, M.D.
- Block 4 of your application does not list Dr. Babu. Please indicate whether Dr. Babu is to be deleted from the list of authorized users.
3. NRC's June 16, 1980 letter to all medical licensees requested that an ALARA program be submitted with significant amendment requests filed after August 15, 1980. Please submit a copy of your ALARA program. You may choose to adopt the Model ALARA Program in Appendix O of Regulatory Guide 10.8. If you have chosen to adopt the model ALARA program, you may simply fill in the blanks on the first and last pages of the program, have a representative of your management sign the program on the last page, and submit the signed model ALARA program with your response to this letter.

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4. Ancillary personnel (clerical, nursing, housekeeping security, etc.) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. Outline your method to assure that these employees receive the necessary instruction. Confirm that this instruction will be given both initially and annually thereafter on a refresher basis.
5. Please submit detailed procedure for calibrating your dose calibrator this procedure should contain the time interval for linearity tests and constancy tests. You may choose to adopt Appendix D of Regulatory Guide 10.8 or you may submit procedures which are equivalent to Appendix D.
6. Concerning your package opening procedures:
 - a. Please confirm that you will wipe the external surface of the final source container, assay the wipe in a low background area, and record the amount of removable radioactivity.
 - b. Confirm that these wipes will be assayed in a low background area with a thin-end-window G-M survey meter or equivalent.

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. 02444.

Sincerely,

Original Signed By:

John E. Glenn
John E. Glenn, Ph.D., Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

Enclosures:

1. Regulatory Guide 10.8
2. NRC Letter June 16, 1980, ALARA Program
3. 10 CFR 31
4. 10 CFR 35

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