MAY 6 1980

FCMLB:JD
030-17488
(03407)

Pharmaco Nuclear, Inc.
ATTN: Frank M. Comer
Health Physicist
100 North Euclid Avenue
Suite 900
St. Louis, MO 63108

Gentlemen:

This is in reference to your application dated April 7, 1980, for a byproduct material license. In order to continue our review, we need the following additional information:

1. Please describe the location of your fume hood stack(s), height above roof level, and relationship to the nearest windows, air intakes, etc.

2. Your application states that written instructions will be provided to individuals who deliver radioactive shipments to the nuclear pharmacy during off-duty hours. In addition, a copy of these instructions should be posted in the area where shipments are placed during off-duty hours. Please confirm.

   Please submit a copy of the written instructions that you will provide. For further guidance, refer to Appendix E (enclosed).

3. Your application states that you will dispose of Tc-99m generators by decay-in-storage. Note that these generators may contain long-lived radioisotopic contaminants. Since you intend to dispose of generators by this method, you should segregate the generator columns so that they may be monitored separately to assure decay to background level prior to disposal. Please confirm.

4. Please submit evidence that your facility is licensed by the Missouri State Board of Pharmacy (e.g., a copy of the pharmacy permit).

5. Your customers must be able to ensure that they have received Group V materials from a distributor licensed pursuant to 10 CFR 32.72. Accordingly, Pharmaco Nuclear, Inc. must provide the licensing statement specified in 10 CFR 32.72(a)(4) on a label, leaflet or brochure that accompanies each Group V radiopharmaceutical. The original manufacturer's statement is not sufficient for this purpose. Please submit an actual sample of the label, leaflet or brochure that you will use on Group V materials.

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6. Please confirm that in-vitro test kits for redistribution to specific licensees will contain labeling that conforms to the requirements in 10 CFR 20.203 (enclosed).

7. The package opening procedures in your radiation safety manual should be equivalent to those in Item 10.b. (page 6) of your application. Your radiation safety manual should be modified accordingly.

8. Presently, it is our policy to require that at least one authorized user be physically present at the nuclear pharmacy whenever licensed material is being used for preparation of radiopharmaceuticals, dispensing, etc. Since radiopharmacy operations may commence during the early hours of the morning and continue throughout the day, you should be certain to name sufficient users to assure that all shifts are covered and to allow for vacations, illness, etc.

We will continue our review of your application upon receipt of this information. Please reply in duplicate and refer to Control No. 03407.

Sincerely,

Joseph DelMedico
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosures:
1. Appendix E
2. 10 CFR Parts 20 and 32

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