UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

FCMLB:MAL
030-10246
(98444)

NOV 8 1979

Veterans Administration Medical Center
ATTN: Anna Polizio, M.D.
New Castle Road
Butler, PA 16001

Gentlemen:

This is in reference to your application dated January 22, 1979, for renewal of Material License No. 37-16034-01. In order to continue our review of your application, we need the following additional information:

1. In support of your request for 10 millicuries of each of the byproduct materials listed in Section 31.11 of 10 CFR Part 31, please provide the following:

   a. Describe your planned bioassay program including the type of bioassays (thyroid counts, urine counts, whole body counts, etc.), the criteria and frequency for performing bioassays, and the type of actions taken when positive results are obtained. For your assistance, we are enclosing tritium and iodine bioassay guides that contain criteria for performing bioassays that we find acceptable.

   b. Describe your procedures for complying with Section 20.1(c), Section 20.103, and Section 20.106 of 10 CFR Part 20 for procedures such as protein iodinations and tritium labeling experiments that may release volatile or gaseous radioactive materials to restricted and unrestricted areas. You should include a description of the type of surveys, e.g., environmental or breathing zone, frequency of surveys, individuals who will perform the surveys, e.g., radiation safety officer or investigator, equipment to be used, and procedures for evaluating the results.

2. In addition to the sources listed in your application, your institution should obtain and use a cobalt-57 source of approximately 3 to 5 millicuries to perform your daily consistency check and annual energy check and a barium-133 source of approximately 100 microcuries to perform your annual energy check.

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Gentlemen:

This is in reference to your application dated January 22, 1979, for renewal of Material License No. 37-16034-01. In order to continue our review of your application, we need the following additional information:

1. In support of your request for 10 millicuries of each of the byproduct materials listed in Section 31.11 of 10 CFR Part 31, please provide the following:

   a. Describe your planned bioassay program including the type of bioassays (thyroid counts, urine counts, whole body counts, etc.), the criteria and frequency for performing bioassays, and the type of actions taken when positive results are obtained. For your assistance, we are enclosing tritium and iodine bioassay guides that contain criteria for performing bioassays that we find acceptable.

   b. Describe your procedures for complying with Section 20.1(c), Section 20.103, and Section 20.106 of 10 CFR Part 20 for procedures such as protein iodinations and tritium labeling experiments that may release volatile or gaseous radioactive materials to restricted and unrestricted areas. You should include a description of the type of surveys, e.g., environmental or breathing zone, frequency of surveys, individuals who will perform the surveys, e.g., radiation safety officer or investigator, equipment to be used, and procedures for evaluating the results.

2. In addition to the sources listed in your application, your institution should obtain and use a cobalt-57 source of approximately 3 to 5 millicuries to perform your daily consistency check and annual energy check and a barium-133 source of approximately 100 microcuries to perform your annual energy check.

3. With regard to your Medical Isotope Committee:

   a. Your institution should appoint a permanent member of your administrative staff to your Medical Isotopes Committee.

   b. You should modify the membership of your Committee to include a physician with expertise in pathology or hematology, internal medicine. In addition, we recommend that a representative of your nursing staff also be included on your Committee.

   c. You should modify the meeting frequency of your Committee to at least once in each calendar quarter.

4. Submit a copy of the instructions provided to your security personnel for receiving packages containing radioactive materials during off-duty hours. Appendix E to Regulatory Guide 10.8 contains a sample memorandum to security personnel that we find acceptable.

5. With regard to your personnel training program:

   a. In addition to the training stated in your application, technical personnel should be instructed in the terms and conditions of your license at least once annually.

   b. Verify that nontechnical personnel will have annual refresher training.

6. With regard to your request for iodine-131 as iodine for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma:

   a. It has been determined that thyroid uptake can occur by breathing volatile iodine which is released when the cap is first removed from vials containing therapeutic liquid iodine-131. Accordingly, personnel should be instructed to wear gloves and to open the vials in a fume hood or take alternative precautionary measures.

   b. Describe the bioassay program to be established for personnel who handle therapeutic liquid iodine-131. As a minimum, thyroid counts should be obtained approximately twenty-four (24) hours after exposure. Refer to the enclosed bioassay guide.

7. With regard to your request for 500 millicuries of xenon-133:

a. Describe the areas in which you plan to store the xenon-133. Include a diagram indicating the availability of shielding material and the proximity to unrestricted areas.

b. Describe the ventilation in all areas where xenon-133 is used and stored. The location of supply and exhaust vents, the measured airflow rates for each vent and the fraction of air that is recirculated by system should be indicated.

c. Describe the emergency procedures to be used in case of an accidental release of xenon-133. This should include such considerations as temporary evacuation of the area or increasing the ventilation in the area.

d. Describe your method of disposal of xenon-133 gas after use. You should include specific calculations of air concentrations for unrestricted areas.

We will continue our review of your application upon receipt of this information. Please reply in duplicate and refer to Control No. 98444.

Sincerely,

Michael A. Lamastra
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosures:
1. Form NRC-313M
2. Regulatory Guide 10.8
3. Tritium Bioassay Guide
4. Iodine Bioassay Guide