MAR 3 1 1980

FCRLB:JD
030-10233
(99949)

Devine Providence Hospital
ATTN: Lee B. Youngquist
Administrator
1004 Arch Street
Pittsburgh, PA 15212

Gentlemen:

This is in reference to your application, dated May 15, 1979, to renew Byproduct Material License No. 37-16031-01. In order to continue our review, we need the following additional information:

1. The preceptor statement that Dr. Pavsek signed for Dr. Hughes does not indicate experience with the materials listed in Groups I and III of 10 CFR 35.100 (enclosed). If Dr. Hughes wishes to be authorized to use these materials, she should submit signed, completed preceptor statements (Form NRC-313M-Supplement B, enclosed), indicating supervised participation in the use of these materials. For Group III, the following is considered acceptable: Personal participation in five procedures to elute Tc-99m from a molybdenum generator, including testing of the eluate for molybdenum contamination, and five procedures to prepare radiopharmaceuticals from Group III reagent kits.

2. Your radiation safety officer should be present on a daily basis in order to direct the radiation safety program. Since it appears that Mr. Durkosh serves in a consultant capacity, you should provide the name of the individua who will assume the duties of radiation safety officer on a day-to-day basis. This individual may be one of the physician users currently listed on your license. If not, this individual should submit Form NRC-313M-Supplement A (enclosed), documenting training and experience equivalent to that specified in Appendix A, Sections 1.a. and 1.b. (enclosed).

3. You should have available a low level survey meter capable of reading 0.02 to 0.5 mR/hr as the maximum on one scale in order to perform accurate contamination surveys, etc. Please specify the manufacturer's name, model number, and lowest level range of the instrument in your laboratory that will fulfill this need.

4. In addition to the daily constancy check that you perform on your dose calibrator, you should perform accuracy tests (annually) and linearity tests (quarterly). Please confirm.

OFFICE ▶					
SURNAME ▶					
DATE ▶					

"OFFICIAL RECORD COPY" ML11

NRC FORM 318 (6-77) ☆ U. S. GOVERNMENT PRINTING OFFICE 1977-237-025

Submit your step-by-step procedures for performing the accuracy and linearity tests, including sources to be used (identified by nuclide, activity, and calibration accuracy). Your procedures and sources should be at least equivalent to those described in Appendix D, Section 2 (enclosed).

The linearity test should be performed using the maximum activity that is assayed in clinical situations (e.g., first elution from a new Tc-99m generator). Proper performance of the constancy and accuracy tests requires at least two reference standards to represent the high and low energy ranges (e.g., cesium-137 and cobalt-57). Source activity levels should approximate those levels normally encountered in clinical use (i.e., cobalt-57: one millicurie or more).

5. On a detailed version of your facility diagram, please indicate the type, dimensions, position and thickness of shielding that you will use for:

   a. Use and storage of Tc-99m generators.

   b. Storage of radiopharmaceuticals (refrigerated and nonrefrigerated).

   c. Preparation and dispensing of Group III kit radiopharmaceuticals (e.g., lead glass L-block, etc.).

6. Your Medical Isotope Committee should include a physician specialist in internal medicine. Refer to 10 CFR 35.11(b). Please submit the name and qualifications (briefly) of the individual on your Committee who will fulfill this need. If such an individual is not available at your hospital because of size or circumstance, you may so state.

7. Your application indicates the use of pocket type dosimeters. Please submit your method for calibrating these dosimeters. Include the frequency of calibration, sources to be used (identify by nuclide, activity and calibration accuracy), and tests to check for drift.

8. Item No. 13 of your application states that an abnormal reading for isotope packing material is considered to be twice background. All materials with a reading in excess of natural background should be disposed of as radioactive waste. Please confirm.

9. Radiation workers (technologists, etc.) must receive instruction as specified in 10 CFR 19.12 (enclosed). Note that many of these items pertain to circumstances at your particular institution; therefore, you may not assume that this instruction has been adequately covered by prior occupational training, Board certification, etc. Please confirm that this instruction will be given both initially and annually thereafter on a refresher basis.

OFFICE ▶						
SURNAME ▶						
DATE ▶						

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.

We will continue our review of your application upon receipt of this information. Please reply in duplicate and refer to Control No. 99949.

Sincerely,

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

Enclosures:
1. 10 CFR Part 35
2. Form NRC-313M-Supplements A and B
3. Appendix D

CRESS:WILLEE ▶	FCMLB SO					
MC#453399:gtw						
SURNAME ▶	JDelMedico:gtw					
3/27/80 DATE ▶	3/28/80					