APR 30 1985

License No. 37-00897-01
Docket No. 030-02971
Control No. 03565

Mercy Hospital
ATTN: S. M. Imperiale, M.D.
25 Church Street
Wilkes-Barre, PA 18765

Gentlemen:

This is in reference to your application dated March 15, 1985 to renew License No. 37-00897-01. In order to continue our review, we need the following additional information:

1. You should have available in your department a high-level survey meter capable of reading up to 1 Roentgen per hour in order to measure radiation dose rates that may exist in the vicinity of Tc-99m generators, etc. Please indicate the manufacturer's name, model number, and highest level range of the instrument in your laboratory that will fulfill this need.

2. A. In Item 6.a of your application, you have requested radioactive material listed in 10 CFR 35.100, Schedule A, Group IV. Although treatment for hyperthyroidism is often performed on an outpatient basis, appropriate procedures should be established because hospitalization is sometimes required. Please refer to Item 19 of Regulatory Guide 10.8 (enclosed) for guidance on acceptable procedures. Please submit procedures to be followed when therapy patients require hospitalization.

   B. Thyroid uptake can occur by breathing volatile iodine which is released when the cap is first removed from vials containing therapeutic liquid iodine-131. Personnel should be instructed to wear gloves and to open the vials in a fume hood or to take alternative precautionary measures.

   A bioassay program should 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.

   Submit the precautionary measures and the bioassay procedures that you will follow or confirm that iodine-131 will only be received and administered as capsules.

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C. You have also requested a possession limit of 30.0 mCi Iodine-131 as Iodide for treatment of thyroid carcinoma. Treatment of thyroid carcinoma using doses of 30 millicuries or less is not recognized in Group IV of 10 CFR 35.100 (enclosed). If you wish authorization for Group V of 10CFR35.100 procedures you need a physician user qualified for Group V procedures. Please clarify.

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. 03565.

Sincerely,

Original Signed By:
John D. Kinneman

John D. Kinneman, Chief
Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards

Enclosures:
1. 10 CFR Part 35
2. Regulatory Guides 10.8, 8.20

RI:DRSS M.P.
Piccone/mlb
4/22/85

RI:DRSS
Kinneman
4/30/85

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