

APR 15 1985

St. Joseph Hospital
Department of Nuclear Medicine
and X-Ray Therapy
ATTN: J. R. Glover, Ph.D.
Radiation Safety Officer
302 Kensington
Flint, MI 48502

License No. 21-01103-04

Re: Letter dated November 27, 1984, to renew NRC License
Number 21-01103-04.

Gentlemen:

In order to complete our review of your request, we need additional
information and/or clarification on the following items:

1. Bioassays

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.

2. Authorized Users

In order to add A. Parillo, M.D., L. Cohen, M.D., B. Chang, M.D., or H. Klosterman, M.D. as authorized users for radiopharmaceuticals in Groups I, II and III, you will need to submit documentation of each physician's training/experience equivalent to that outlined in Sections II, III, IV, and V of Appendix A as printed in the enclosed December 2, 1982 Federal Register. The Supplement A's included with your application do not specify any actual "hands-on" experience with radiopharmaceuticals, preparation of reagent kits, elution of generators, or clinical training.

3. Please submit a description of the area(s) where byproduct material listed in Section 31.11(a) of 20 CFR Part 31 will be utilized for In Vitro studies. The description should include security, access control and waste disposal facilities.

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If you have any questions or require clarification on any of the information stated above, you may contact us at (312) 790-5625.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 77887.

Sincerely,

Original Signed By
B. S. Mallett, Ph.D., Chief
Materials Licensing Section

Enclosures:

1. Regulatory Guide 8.20
2. December 2, 1982 Federal Register

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WJH
for Mallett/jl
3/28/85