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JUL 23 1985

Heartland Hospital West
ATTN: Mr. M. McGeehan, Director
Radiology and Medical Imaging
Seventh to Ninth on Faraon
Saint Joseph, MO 64501

Gentlemen:

We have reviewed your application dated May 16, 1985 requesting renewal of License Number 24-13246-01 and find that we will need additional information as follows:

1. Concerning your request to add Dr. E. Reddy to your license to use Iodine-125 seeds, iridium-192, cesium-137 and phosphorus-32, please note the following:

   a. Your current license does not authorize the possession or use of iridium-192 or cesium-137 for brachytherapy. If you wish to add Group VI to your license, please submit the appropriate information as addressed in Regulatory Guide 10.8, Item 20, page 10.8-11 and in Appendix L.

   b. In order for Dr. Reddy to be authorized to use phosphorus-32 for therapy you must submit documentation that he has been previously licensed for this use or submit documentation of his training and experience treating at least three patients with soluble P-32 for treatment of polycythemia vera and/or bone metastases and at least three patients with colloidal P-32 for treatment of malignant effusion. This information should be submitted on a Preceptor Statement and signed by his preceptor. See Regulatory Guide 10.8.

   c. The previous license number that you referenced for Dr. Reddy (24-16178-01) authorized him to use iodine-125 seeds only. Therefore, he will be added to your license for use of iodine-125 seed.

2. You have indicated that your xenon-133 use will be approximately 50 millicuries per week. Please justify why you need a possession limit of 1 curie. We feel your possession limit should be more closely in line with your actual need.

3. In your application you have requested possession and use of iodine-131 for treatment of thyroid carcinoma. To obtain this authorization you must state who will use or supervise the use of this material and demonstrate that each of these physicians have had the necessary experience and training or have been previously licensed for this use. For the required training refer to Regulatory Guide 10.8, Appendix A, Item 4.b., for Group V, on page 10.8-16. Submit this information on a Preceptor Statement signed by a preceptor.

4. Before iodine-131 for thyroid carcinoma is added to your license, you must describe your precautions and procedures including the following:

   a. 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, Regulatory Guide 8.20.

      Submit the precautionary measures and the bioassay procedures that you will follow.

   b. Since procedures submitted in your application dated May 16, 1985, page 9 of Item 19, address only Group IV activities and because the use of iodine-131 for treatment of thyroid carcinoma is a Group V procedures, submit the information requested in Regulatory Guide 10.8, Item 19, page 10.8-10.

5. Your procedures for linearity test for the dose calibrator state "a set of calibrated lead absorbers similar to the calicheck or lineator systems will be used...". If you will be using a system other than the Lineator or Calicheck, please submit information on the system including a complete physical description, and step-by-step calculations and procedures for its use for our evaluation and approval. If you will only use the Lineator or Calicheck system please so state.

6. Please submit a diagram of your nuclear medicine facilities. The diagram that you referenced in your application was not enclosed with the application.

7. Describe the storage location, security and shielding for the iodine-125 seeds.

8. During a telephone conversation with Mr. Bob LaDue of Heartland Hospital East on July 18, 1985, we became aware that Heartland Hospital East will transfer radiopharmaceuticals to Heartland Hospital West. Therefore, submit the following:

   a. Modify the procedures enclosed in your application under Miscellaneous Information to reflect that Heartland Hospital West will receive radiopharmaceuticals from Heartland Hospital East.

b. Include in your response a statement or signature from your hospital's administrator that he or she concurs with these procedures.

c. Confirm that any individual doses received form Heartland Hospital East will be calibrated in the dose calibrator at Heartland Hospital West prior to administration to the patient.

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 79080.

Sincerely,

Original Signed By
Evelyn R. Matson
Materials Licensing Section

Enclosure: Regulatory Guides 8.20
and 10.8

RIII
Matson/cm
07/19/85