

File

APR 15 1985

Mercy Hospital  
ATTN: M. M. Riepe  
Acting President  
800 Mercy Drive  
Council Bluffs, IA 51502

License No. 14-13474-01

Gentlemen:

We have reviewed your letter dated March 8, 1985 requesting an amendment to License No. 14-13474-01 and find that we will need additional information as follows:

1. Submit documentation of Dr. Van de Water's training in basic radioisotope handling techniques. This training should be at least equivalent to that outlined in Section 2.a of Appendix A of Regulatory Guide 10.8. This documentation should be submitted on Supplement A of NRC Form-313M.
2. Please submit the information requested in Item 5 of NRC Form-313M Supplement A to describe Dr. Van de Water's experience actually handling radioactive material. This experience may have been obtained in conjunction with Dr. Van de Water's clinical training, but should be described separately to differentiate this part from patient examination, image interpretation, etc.
3. Please indicate any continuing education or experience Dr. Van de Water has received from July 1978 to the present. The Advisory Committee on the Medical Uses of Isotopes has indicated that it will not consider training in basic radioisotope handling techniques and supervised clinical training in excess of five years from the date of application, unless the applicant has interim experience under some byproduct material license.
4. It appears from Item 3 of Preceptor Statement that Dr. Van de Water spent 3 months training at the University of Colorado and 1 month at the Veterans Administration Hospital. It is not clear if the preceptor, Dr. William Hennee, is located at both institutions and supervised Dr. Van de Water for all of the cases listed on the preceptor form. Please clarify, and if appropriate submit one preceptor statement completed and signed for each preceptor supervising his clinical training. Also specify the total number of hours received in clinical radioisotope training (Item 3.).

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5. From the preceptor statement submitted, it is not clear that Dr. Van de Water has personally participated in five procedures to elute Tc-99m, including testing eluates, and five procedures to prepare radiopharmaceuticals from Group III reagent kits. In order to be approved for Group III procedures, he must submit clear documentation and/or obtain the necessary experience for the above procedures. This experience can be obtained under the supervisions of Dr. Keefe of your staff.

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 78490.

Sincerely

Original Signed By  
Evelyn R. Matson  
Materials Licensing Section

Enclosure: Regulatory Guide 10.8

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Matson/jl  
4/12/85