

November 12, 1984

Holland Community Hospital  
ATTN: Wayne Wallace, R.T.  
602 Michigan Avenue  
Holland, MI 49423

Gentlemen:

This is in reference to your letter, dated October 29, 1984, to amend Byproduct Material License No. 21-18502-01. In order to continue our review, we need the following additional information:

1. Your letter should have been signed by the hospital administrator (not Wayne Wallace). Please submit a letter from the hospital administrator indicating that he or she has reviewed the letter and concurs in the statements and representations contained therein. Note also that the hospital administrator should sign all future correspondence, requests for amendment, renewal, etc.

2. Dr. David J. Mulligan, has not documented a sufficient number of hours of training in basic radioisotope handling techniques to meet the criteria specified in Item 2.a., Appendix A of Regulatory Guide 10.8 (enclosed). Therefore, please provide documentation of the total number of hours required. If Dr. Mulligan has not received the minimum number of hours requested, we recommend that you withdraw your request at this time and reapply at a later date when a sufficient number of didactic hours has been obtained.

When you reply, be certain to specify the additional hours in Item 4 of Form 313M-Supplement A attached to Regulatory Guide 10.8.

3. We must receive a detailed description of the individual isotopes and the amounts of each isotope that Dr. David J. Mulligan has had experience with during the past five years, the duration of experience, the type of use and the institution(s) where the experience was obtained. We would expect the type of use to include:

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- a. Ordering, receiving, and unpackaging radioactive materials safely, including performance of the related radiation surveys.
- b. Calibration of dose calibrators and diagnostic instrumentation, and performance of operational checks on survey meters.
- c. Calculation, preparation and calibration of patient doses, including radiation safety considerations.
- d. Administration of doses to patients, including proper use of syringe shields.
- e. Appropriate internal control procedures to prevent the misadministration of materials to patients.
- f. Emergency procedures to handle and contain spilled materials safely, including related decontamination procedures.

The information that you submit must be adequate to fulfill the criteria of 500 hours as set forth in Appendix A, Section 2.b. of Regulatory Guide 10.8. If Item 5 on Form 313M-Supplement A does not provide enough room for detailed account, you may expand this format to a full page.

We will continue our review of your application upon receipt of this information. Please reply in duplicate within 30 days and refer to Control No. 77727.

If you have any questions please call us at (312)-790-5625.

Sincerely,

*Evelyn Matson*

Evelyn Matson  
Material Licensing Section

Enclosures:  
Regulatory Guide 10.8

REGION 3

Matson *EM*

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