

OCT 17 1985

License No. 37-12141-01
Docket No. 030-03158
Control No. 104427

Metropolitan Hospital-Parkview Division
ATTN: Irvin Berland
Administrator
1331 East Wyoming Avenue
Philadelphia, Pennsylvania 19124

Gentlemen:

This is in reference to your request in a letter dated September 23, 1985 to amend License No. 37-12141-01. In order to continue our review, we need the following additional information:

1. Item 5 of NRC form 313M, Supplement A submitted for Dr. David Masiak was left blank. We must receive a detailed description of the individual isotopes and the amounts of each isotope that Dr. Masiak 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:
 - a. Ordering, receiving, and unpackaging radioactive material 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 set forth in Appendix A, Section 2.b. If Item 5 on Form 313M-Supplement A does not provide enough room for a detailed account, you may expand this format to a full page.

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2. Dr. Masiak has not documented a sufficient number of hours in clinical radioisotope training to meet the training and experience criteria specified for diagnostic studies limited to nuclear cardiology. For physicians who began their nuclear cardiology training prior to July 1, 1984, the requirement is 250 hours of clinical training in an institutional nuclear medicine/nuclear cardiology program.

At least 50% of this time should be devoted to nuclear cardiology studies. The clinical training should include:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed.
2. Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurement and plotting data.
3. Follow-up of patients when required.
4. Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindication, etc.

In support of your request, you should therefore submit additional preceptor statements to document the required training.

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. 104427.

Sincerely,

Original Signed By:
Josephine M. Piccone

Josephine M. Piccone, Ph.D.
Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards

RI:DRSS *J.M.P.*
Piccone/mlb
10/16/85

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