



REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

April 30, 2009

Docket No. 03033000
Control No. 143678

License No. 29-30003-01

Kock-Yen Tsang, M.D.
Medical Director
Ocean Heart Imaging
9 Hospital Drive
Toms River, NJ 08755

SUBJECT: OCEAN HEART IMAGING, REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL
NO. 143678

Dear Dr. Tsang:

This is in reference to your letter dated April 23, 2009 requesting to amend Nuclear Regulatory Commission License No. 29-30003-01. In order to continue our review, we need the following additional information:

Please confirm that Stephen Fedec, D.O., FACC has performed the following experience elements during his training:

- (A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (C) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
- (E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
- (F) Administering dosages of radioactive drugs to patients or human research subjects; and
- (G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

K. Tsang

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We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 143678. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Dennis R. Lawyer

Dennis R. Lawyer
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:

John P. West, C.N.M.T., Radiation Safety Officer

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