



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

March 21, 2006

Docket No. 03035122  
Control No. 138396

License No. 29-30525-01

Howard Goldschmidt, M.D.  
President  
Valley Heart Group  
Parkview Plaza  
1200 East Ridgewood Avenue, 2 East  
Ridgewood, NJ 07450

SUBJECT: VALLEY HEART GROUP, REQUEST FOR ADDITIONAL INFORMATION  
CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL  
NO. 138396

Dear Dr. Goldschmidt:

This is in reference to your letter dated January 30, 2006 requesting to amend Nuclear Regulatory Commission License No. 29-30525-01. In order to continue our review, we need the following additional information:

- 1) The request for Dr. Mitchell to become an authorized user followed the training requirements as stated in 10 CFR 35.920. However, as of October 24, 2005, 10 CFR 35.290 must be followed for 10 CFR 35.200 material authorization. Please supply information that demonstrates Dr. Mitchell's training and experience that complies with:

©)(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum—

(I) Classroom and laboratory training in the following areas—

- (A) Radiation physics and instrumentation;
- (B) Radiation protection;
- ©) Mathematics pertaining to the use and measurement of radioactivity;
- (D) Chemistry of byproduct material for medical use;
- (E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290, or 35.290(c)(1)(ii)(G) and 35.390, or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements, involving—

- (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;
- ©) 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; and documented on your written attestation statement.

It is recommended to use Form 313A when documenting authorized user's training.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, Industrial, and Academic Uses of Nuclear Material**; then **Toolkit Index Page**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

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. 138396. 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

Enclosure:  
NRC Form 313A

DOCUMENT NAME: E:\Filenet\ML060820411.wpd

**SISP Review Complete: DLawyer**

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