



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

July 5, 2006

Docket No. 03034622
Control No. 139040

License No. 37-30426-01

Eric E. Weis
CEO
The Heart Group, Ltd.
1810 Oregon Pike
Lancaster, PA 17601-6470

SUBJECT: THE HEART GROUP, LTD., REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL
NO. 139040

Dear Mr. Weis:

This is in reference to your letter dated June 19, 2006 requesting to amend Nuclear Regulatory Commission License No. 37-30426-01. In order to continue our review, we need the following additional information:

1. Certain experience elements as required by 10 CFR 290(c)(ii) were not included in the attestation statement by Dr. Abass Alavi. These experience elements are:
 - (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.

E. Weis
The Heart Group, Ltd.

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Please include these experience elements, clock hours, dates of experience, location, and name of supervising individual in an attestation statement signed by an qualified authorized preceptor.

2. Because, the preceptor, Dr. Alavi, is an authorized user at a broad scope facility, we can not verify his qualification. Please provide documentation that Dr. Alavi is an authorized user for 35.100 and 35.200 materials at the Hospital of the University of Pennsylvania. Normally, documentation would be signed by the Radiation Safety Officer of that facility.

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 **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 8:00 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. 139040. 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:
Neil R. Clark, M.D., Radiation Safety Officer

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SUNSI Review Complete: DLawyer

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