

From: Dennis Lawyer
To: Cranburyhl@yahoo.com
Date: Wed, Apr 5, 2006 1:14 PM
Subject: Cranbury Heart and Lung Associates, request for additional information

License No.:29-31139-01
Docket No: 03037175
Control No: 138576

Cranbury Heart and Lung Associates, Request for Additional Information Concerning Application for a New License, Control 138576

Dear Dr. George Logothetis,

This is in reference to your application dated March 7, 2006 requesting for new Nuclear Regulator Commission License No. 45-24869-01. In order to continue our review, we need the following additional information:

- 1) The application was missing some required attributes to approve you as an authorized user. The training and experience requirements to be an authorized user per the requirement as listed in 10 CFR 35.290. The regulation may be found at <http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0290.html>. In particular, classroom and laboratory training was not documented for a) mathematics pertaining to the use and measurement of radioactivity and b) Radiation biology. Work experience did not state the following requirements: a) Calculating, measuring, and safely preparing patient or human research subject dosages and b) 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. A preceptor should attest to this training and experience.
- 2) The application was missing documentation of the training and experience requirements to qualify you as a Radiation Safety Officer. The training and experience requirements are listed in 10 CFR 35.50. The regulation may be found at <http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0050.html>. Please submit the documentation in support of this position. It is recommended that you use NRC Form 313A located at <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a.pdf>. Alternatively, you may appoint a different person to this position.
- 3) The preceptor, Dr. Richard M. Hayes, is an Authorized User on a license in an agreement state. Please submit a copy of the license that lists Dr. Hayes as and Authorized User.
- 4) Please describe what is located above and below areas in which byproduct materials will be used or prepared for use. This request is based on guidance listed in section 8.15 of NUREG-1556, Volume 9, Revision 1, 'Program-Specific Guidance About Medical Use Licenses.'

We will continue our review upon receipt of this information. Please reply to my attention at the Region 1 Office and refer to Mail Control No. 138576. If you have technical questions regarding this letter, please call me at (610) 337-5366.

Please note that you may not reply to this letter by return e-mail. Your reply must be in writing by letter or facsimile (610-337-5269). If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your application.

Mail Envelope Properties

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From: Dennis Lawyer

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Cranburyhl (Cranburyhl@yahoo.com)

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MESSAGE	4348	Wednesday, April 5, 2006 1:14 PM

Options
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