

UNITED STATES NUCLEAR REGULATORY COMMISSION

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

November 2, 2005

Docket No. 03036917 License No. 32-31038-01

Control No. 137750

Steven W. Walter, M.D. Radiation Safety Officer Corscan 740A NW Broad Street Southern Pines, NC 28387

SUBJECT: CORSCAN, REQUEST FOR ADDITIONAL INFORMATION CONCERNING

APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 137750

Dear Dr. Walter:

This is in reference to your letter dated September 12, 2005 requesting to amend Nuclear Regulatory Commission License No. 32-31038-01. In order to continue our review, we need the following additional information:

- 1. In support of your request to authorize Dr. Jonathan Sheinberg for materials permitted under 10 CFR 35.200, please provide a copy of the Texas license which indicates that Dr. Sheinberg's preceptor, John T. Hays, M.D. is an authorized user. This is needed because we do not maintain copies of agreement state licenses.
- 2. In support of your request to authorize Dr. Beth Bartholomew for materials permitted under 10 CFR 35.200, please provide:
 - A. Documentation that Dr. Bartholomew's preceptor, Christine Z. Dickinson, M.D. is an authorized user. A letter from the broadscope licensee's Radiation Safety Officer verifying Dr. Dickinson authorization would be acceptable. This is needed because William Beaumont Hospital has a broadscope license and does not specifically list authorized users.
 - B. The preceptor written attestation by Christine Z. Dickinson, M.D. did not state that Dr. Beth Bartholomew's **work experience** included:
 - (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (3) Calculating, measuring, and safely preparing patient or human research subject dosages;

- (4) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
- (5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
- (6) Administering dosages of radioactive drugs to patients or human research subjects; and
- (7) 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.

Satisfactorily completing these work experiences are minimum requirements as listed in 10 CFR 35.290(c)(2). Please confirm this training by an authorized preceptor written attestation.

- 3. In support of your request to authorize Dr. Belinda Ng for materials permitted under 10 CFR 35.200, please provide the following:
 - A. A copy of the Illinois license which indicates that Dr. Ng's preceptor, Thomas A. Holly, M.D. is an authorized user. This is needed because we do not maintain copies of agreement state licenses.
 - B. Written attestation, signed by a preceptor physician authorized user, that the listed experience has been satisfactorily completed. The preceptor's statement did not include the number of hours experience nor did it state that it included the minimum work experience requirements which include:
 - (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (4) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
 - (5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
 - (6) Administering dosages of radioactive drugs to patients or human research subjects; and

(7) 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, 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. 137750. If you have any technical questions regarding this deficiency letter, please call Dennis Lawyer (610) 337-5366 or me at (610) 337-5303.

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 Thomas K. Thompson

Thomas K. Thompson Senior Health Physicist Commercial and R&D Branch Division of Nuclear Materials Safety

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SISP Review Complete: <u>DLawyer</u>
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