From: Weidner, Tara
Sent: Thursday, July 14, 2011 11:12 AM
To: 'lshomsky@connonc.com'
Subject: NRC request for additional information

Licensee: Connecticut Oncology and Hematology
License Number: 06-31418-01
Docket Number: 03038340
Mail Control: 575248

To: Lisa Shomsky, Manager

Additional information is needed for the NRC to continue its review of your amendment request. Please provide the following information August 1, 2011:

1. You requested that the Radiation Safety Officer (RSO) be changed to Sadek Nehmeh, Ph.D. A preceptor form, signed by K. Paul Steinmeyer, was provided as evidence of Dr. Nehmeh's training and experience. Upon reveiew of the preceptor form, I noticed that one of the sections (Part II – Preceptor Attestation, Second Section) was not addressed. In order to approve Dr. Nehmeh as the RSO, he will need to acquire training in the radiation safety, regulatory issues, and emergency procedures for the use of 35.200 and 35.300 materials (oral administration of iodine 131 less than 33 millicuries and parenteral administration of any beta emitter, or photon-emitting radionuclide with photon energy less than 150keV). Following the training, please update Dr. Nehmeh's preceptor form (Part II – Preceptor Attestation, Second Section) to confirm that he has received the training.

2. Your current license authorizes the use of Flourine-18 for calibration of instruments. Please confirm whether or not Dr. Nehmeh will calibrate your instruments and describe his training in such.

3. You also requested authorization for 10 CFR 35.300 materials. Please specify the types of 35.300 procedures that you wish to perform, for example, which types of radiopharmaceutical therapy (Bexxar, Zevalin, Quadramet, and/or Metastron). Please note that Dr. Go's 35.300 authorization on the Charlotte-Hungerford is limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries, Sr-89, and Sm-153. If you wish to perform other procedures, please describe Dr. Go's recent training and experience for these.

4. Also identify the location in your facility where you wish to administer 35.300 materials, describe in detail any shielding, and confirm that you will limit your 35.300 use to administrations for which the patient may be released under the provisions of 10 CFR 35.75.

5. Confirm that all policies and procedures have been updated to include the use of 35.300 materials.

6. Finally, provide the total possession limit for the 35.300 materials.

Please provide a written response to these items under signature of senior management. You may provide this to my attention by letter, fax (610-337-5269), or e-mail of a scanned signed copy, referencing mail control 575248. If we do not receive a reply by August 1, 2011, we shall assume that you do not wish to pursue your application.

Please send a return e-mail to confirm that you received this message.

Tara L. Weidner
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Medical Branch
NRC Region I
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