



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2343 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

JUL 14 2010

Zhongshan (John) Zhang, M.Sc.
Radiation Safety Officer
Oncology Hematology Associates
3699 Epworth Road
Newburgh, IN 47630

Dear Mr. Zhang:

This refers to your letter dated April 1, 2010, making a notification to your NRC Material License No. 13-32700-01.

This also refers to the telephone conversation between you and me on July 13, 2010, concerning the letter dated April 1, 2010, and information that it did not include.

In your letter you requested the addition of Saiyid M. Shah, Ph.D. as an Authorized Medical Physicist (AMP) to your license in order for Dr. Shah to cover your high dose rate remote afterloading brachytherapy (HDR) program during several dates in April 2010. Your letter also referenced the NRC license on which Dr. Shah is already an AMP.

In reviewing the referenced license for Dr. Shah, I discovered that he is an AMP for a different make and model of HDR device than the one on your NRC license.

As your letter dated April 1, 2010, states that it is a "notification," I reviewed 10 CFR 35.13(b)(4)(i), excerpt as follows (emphasis added):

"A licensee shall apply for and must receive a license amendment—

(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except--

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist--

(i) On a Commission or Agreement State license or other equivalent permit or license recognized by NRC that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy."

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I also reviewed 10 CFR 35.14(a)(3), excerpt as follows (emphasis added):

“(a) A licensee shall provide the Commission a copy of the board certification and the written attestation(s), signed by a preceptor, the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, the permit issued by a Commission master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, and for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under § 35.13(b). For individuals permitted to work under § 35.13(b)(4), within the same 30-day time frame, the licensee shall also provide, as appropriate, verification of completion of:

- (1) Any additional case experience required in § 35.390(b)(1)(ii)(G) for an authorized user under § 35.300;
- (2) Any additional training required in § 35.690(c) for an authorized user under § 35.600; and
- (3) Any additional training required in § 35.51(c) for an authorized medical physicist.”

10 CFR 35.51(c) is excerpted as follows (emphasis added):

“Except as provided in § 35.57, the licensee shall require the authorized medical physicist to be an individual who—

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(2) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

- (1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
- (2) Have 2 years of full-time practical training and/or supervised experience in medical physics—
 - (i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or
 - (ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in § 35.57, 35.490, or 35.690; and

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(3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(b)(1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

(iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (a)(2), or (b)(1) and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in §§ 35.51, 35.57, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(c) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization."

The Guidance for the Completion of Forms NRC 313a Series, copy attached, states the following in an excerpt (emphasis added):

"Item 2. Current Authorized Medical Physicist Seeking Additional Uses(s) Checked above

Provide the requested information (i.e., documentation of device-specific training (complete the table in 3.c) and complete the Preceptor Attestation in Part II). As indicated on the form, additional information is needed if the device-specific training was completed more than 7 years ago.

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Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising medical physicist provided the training, identify each supervising individual by name and provide his/her qualifications.”

In our telephone discussion on July 13, 2010, it was not clear whether Dr. Shah had received device-specific training within the previous seven years, i.e., seven years prior to April 1, 2010, and whether he had received training in the operation and emergency procedures, etc. for your make and model of HDR device.

If you wish to pursue this request to add Dr. Shah to your license as an AMP for your HDR program, please provide evidence that he has had device-specific training within the previous seven years, especially training in the operation and emergency procedures, etc. for your make and model of HDR device. As noted above, either the vendor or another AMP, such as you, may provide and document this training for Dr. Shah.

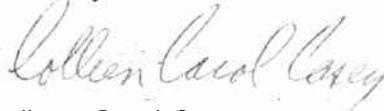
Please submit your request as “additional information to control number 318992” and reference it to my attention. We will then continue our review.

Since we were unable to approve this request at this time, we have “voided” it, or removed it from our active database, pending the receipt of a written response. This action is taken without prejudice to your resubmittal at a later date.

If you have any questions or comments concerning this matter please contact me at (630) 829-9841.

In accordance with 10 CFR 2.390 of the NRC’s “Rules of Practice,” a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC’s Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 13-32700-01
Docket No. 030-37836

Enclosure:

Guidance for Completion of
Forms NRC 313a Series