

From: Gabriel, Sandra
Sent: Monday, November 01, 2010 4:19 PM
To: jfurrow@arh.org
Subject: Additional information for NRC license amendment request, mail control 573703
Attachments: nrc313a(aud).pdf

Licensee: West Virginia Appalachian Regional Healthcare, Inc.
License No.: 47-17725-02
Docket No: 03029017
Control No: 573703

To: Jerome Furrow, Director of Medical Imaging

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

This is regarding your NRC license amendment request dated October 6, 2010. The following additional information is needed to allow us to continue our review of your request to add an authorized user to your NRC license.

- 1) Please clarify the name of this physician—you requested to add Asaithambi Ganesh, M.D., however the supporting documentation refers to Ganesh Asaithambi, M.D.
- 2) In order to authorize this physician for the 35.100 and 35.200 uses on your license, it is necessary to document completion of all of the requirements in one of the pathways in 10 CFR 35.290. It appears that you are requesting to approve this physician under the “training and experience” pathway; therefore it is necessary to provide documentation for 35.290(c)(1)(i) and (ii) and (c)(2).
 - a) 35.290(c)(1) requires completion of a total of 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training in the topics listed in 35.290(c)(1)(i) and supervised work experience in the areas listed in 35.290(c)(1)(ii). It is necessary to document completion of a full 700 hours of training in the specified areas.
 - i) 35.290(c)(1)(i): For classroom and laboratory training, you provided two training certificates, one showing 100 hours of classroom and laboratory training in radioisotope handling techniques provided between February 13-21, 2010, and one showing HAZMAT training on February 21, 2010. Please provide a detailed curriculum demonstrating how the stated number of hours of training in radioisotope handling techniques was provided in a nine-day time period, and confirming inclusion of each of the required topics:
 - Radiation physics and instrumentation;
 - Radiation protection;
 - Mathematics pertaining to the use and measurement of radioactivity;
 - Chemistry of byproduct material for medical use; and
 - Radiation biology.

- ii) 35.290(c)(1)(ii): For supervised work experience, your amendment request provided information about clinical experience, but did not appear to address the radioisotope handling tasks listed in the regulation. Please provide documentation demonstrating completion of supervised work experience [totaling 700 hours in combination with the classroom/laboratory training] including:
- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation safety surveys;
 - Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - Calculating, measuring, and safely preparing patient dosages;
 - Using administrative controls to prevent a medical event;
 - Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
 - Administering dosages of radioactive drugs to patients; and
 - 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.
- b) 35.290(c)(2) requires a written preceptor attestation by a preceptor authorized user. Under the “training and experience” pathway, this should state something like: “Dr. _____ has satisfactorily completed the requirements in 10 CFR 35.290(c)(1)(i) and (ii) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 35.100 and 35.200.” You submitted a copy of a letter dated 6/24/10 from Faye Shamoon, M.D. to the Certification Board of Nuclear Cardiology stating that Dr. Asaithambi completed 80 hours of classroom and laboratory training that meets the NRC requirements.

Dr. Shamoon’s letter did not address the full requirements for 700 hours including supervised work experience in radioisotope handling tasks in 35.290(c)(1)(ii). Please provide a new preceptor attestation addressing all of the required information. The attestation is not required to be signed by the individual who supervised the training—it may alternatively be signed by another authorized user (e.g., an AU who is already listed on your license) who has verified completion of the training and experience and concurs that the applicant satisfactorily completed the requirements and is competent to function independently. As always, the expectation is that the licensee will also verify that all information about training and experience is complete and accurate.

If you wish, you may provide the requested information on NRC Form 313A(AUD), however this is not required. We noted that you included a copy of Form 313A(AUD) with your application, but the only sections completed were the name, State where licensed, and requested authorizations. Another copy of the form is attached to this message.

Please note that you may not reply to this letter by return e-mail. Please send a response, under signature of senior management, to my attention to the Region I office, referencing mail control 573703. This may be sent by mail or by fax to 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.

Thank you for your cooperation. Please feel free to contact me by telephone or e-mail if you have any questions.

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E-mail Properties

Mail Envelope Properties ()

Subject: Additional information for NRC license amendment request, mail control
573703
Sent Date: 11/1/2010 2:17:07 PM
Received Date: 11/1/2010 4:18:00 PM
From: Gabriel, Sandra

Created By: Sandra.Gabriel@nrc.gov

Recipients:
jfurrow@arh.org (jfurrow@arh.org)
Tracking Status: None

Post Office:

Files	Size	Date & Time
MESSAGE	326141	11/1/2010
nrc313a(aud).pdf	299640	

Options

Expiration Date:
Priority: olImportanceNormal
ReplyRequested: False
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Sensitivity: olNormal
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