From: Lanzisera, Penny
To: Miller, Gregg
Subject: Request for Additional Information for Amendment
Date: Wednesday, May 02, 2018 12:11:00 PM

Licensee: District Hospital Partners, dba The George Washington University Hospital
License No. 08-30607-01
Docket No. 03035424
Mail Control No. 602675

Mr. Miller, to support medical use of the remote afterloader, in addition to the information provided in your letter dated February 27, 2108 (2018); please provide the following:

1. Please provide the complete training for at least one authorized user (AU) and one authorized medical physicist (AMP) for use of the device upon completion of installation and training by the manufacturer. In particular:

    a. Dr. Sarfaraz has supplied a copy of his board certification from 1990 and a copy of a Maryland license for manual brachytherapy use only. The board certificate pre-dates the approval of the board by NRC and does not include "AMP Eligible" above the seal and therefore does not fully meet the board certification pathway. NRC approved board certificates are located at https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html. Additionally, the Maryland license does not support Dr. Sarafaz's prior training and experience for remote afterloaders. Therefore, Dr. Sarafaz should complete Item 3 in Form 313A (AMP) and obtain a preceptor attestation from an AMP authorized for remote afterloader use to document his training and experience. A copy of the license listing the preceptor AMP should also be provided. The form is located at https://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(amp).pdf

    b. Complete NRC Form 313A (AUS) for at least one AU to be authorized for medical use. The form is located at https://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aus).pdf

    c. If these individuals (AU and AMP) will also provide future training on use of the device, equivalent to the vendor training, this should be indicated. Please confirm that training and experience of subsequent users (AUs and AMPs) will be documented as described above and include all topics in 10 CFR 35.690(c) and 10 CFR 35. 35.51(c), as applicable; including clinical use and treatment planning software use.

You may provide the above information to my attention either via signed pdf or via fax to 610-337-5269. Please include Mail Control Number 602675 in your response. If you are unable to provide the information within 30 days of the date of this request, we will consider that you no longer wish to pursue medical use of this device at this time and will void your request. Please contact me with any questions.

Penny Lanzisera
Senior Health Physicist