

Walt, GERALYN

From: Lanzisera, Penny
Sent: Friday, April 15, 2016 9:56 AM
To: Moore, Marleen M.
Subject: Dr. Shields

License Number 44-10187-03
Docket No. 03003289
Mail Control 590320

Marleen, I have completed my review of the documentation submitted for Dr. Shields. I have no further questions on his Sirsphere training. However, for the Therasphere training, I did not see documentation to support the following:

“Has successfully completed training in the operation of the delivery system, safety procedures, and clinical use for each type of Y-90 microsphere for which authorization is sought. This requirement may be satisfied by satisfactory completion of a training program provided by either:

1. (Pathway 1) an AU who is authorized for the type of microsphere for which the individual is seeking authorization. This clinical use experience should include at least three supervised hands-on cases for each type of Y-90 microsphere for which the individual is seeking AU status; or
2. (Pathway 2) a Y-90 microsphere manufacturer with documentation.”

You submitted documentation from the preceptor which indicated that Dr. Shields “performed the initial angiogram, reviewed the MAA lung shunt imaging, determined the volume of liver that would be treated based on the MAA SPECT imaging, and using the approved Therasphere methodology, determined the activity and time of administration for treatment.” You also submitted documentation from MDS Nordion that indicated that Dr. Shields participated in a training program in 2008 that “meets the training and experience specified in paragraph two of the NRC guidance.” Neither of these documents confirms that Dr. Shields “has successfully completed training in the operation of the delivery system, safety procedures, and clinical use for” Theraspheres. In addition, neither document addresses whether Dr. Shields was proctored for at least 3 cases and is acceptably trained to administer to Theraspheres to patients.

Please provide additional documentation to support this.

In addition, as discussed with you yesterday, your request to add Dr. Reynolds requires the following additional clarifications to determine how to proceed:

- You documented 125 hours of classroom related training that would be completed in the Radiology Residency training and the 313A (AUD) and (AUT) documents 200. Why the discrepancy?
- Did Dr. Reynolds complete the Radiology Residency? Was the Radiology Residency program accredited? By who?
- Dr. Reynolds provided a plan to complete his Radiology Residency and also complete Nuclear Medicine training during that Residency with a possible 12 months of service in NM completed (with the NM portion not qualifying for ACGME accreditation). Was the 12 months of service in NM completed? Why is this training not accredited?
- Dr. Reynolds participated in administrations involving I-131 and Ra-223. Did Dr. Reynolds participate in any training involving beta emitters used for therapy?

You may fax the additional information to my attention to 610-337-5269. Alternatively you may send a signed pdf via email. Please confirm that you have received this email and respond within 30 days with the additional information.

Thank you for your assistance,

Penny Lanzisera
US NRC, Region I