

From: [Lanzisera, Penny](#)
To: [Wen, Carol](#)
Subject: Request for Additional Information for 2 Amendment Requests
Date: Wednesday, September 12, 2018 10:47:00 AM

Licensee: Christiana Care Health Services, Inc.
License No. 07-12153-02
Docket No. 03001303
Mail Control No. 609482

Dear Ms. Wen, upon review of the amendment requests submitted July 20 and August 27, 2018, please provide the following additional information to support approval:

For Dr. Shukla:

1. Please provide the documentation from Thomas Jefferson University to support that the preceptor, Dr. Den, is an approved authorized user for manual brachytherapy. Documentation submitted with your letter dated April 30, 2018 appears to indicate brachytherapy for HDR only and the letter dated July 20, 2018 did not include the attachment for Dr. Den. In addition, Dr. Shukla's Delaware Medical License was not included; however, this information was confirmed on-line.
2. Please submit documentation indicating that an authorized user or medical physicist for manual brachytherapy and an authorized user or medical physicist for HDR have provided Dr. Shukla training on your operating and emergency response procedures.

For Dr. Francis:

1. In reviewing documentation submitted with your prior amendment, it is unclear whether Dr. Francis completed a Nuclear Medicine Residency program or a Diagnostic Radiology Residency program. Please submit documentation to support the residency program completed by Dr. Francis.
2. Please submit documentation indicating that an authorized user has provided training and Dr. Francis has successfully completed training for both SirSpheres and TheraSphere in:
 - a. the operation of the delivery system
 - b. safety procedures, including operating and emergency procedures
 - c. clinical use applications, including procedures for written directives, the manufacturer's procedures for calculating and documenting the dose or activity to the treatment site, procedures for preparing the dose for administration, determining shunting to non-treatment sites, and performing pre- and post-vial dose measurements; and
 - d. medical event reporting.

In addition, please note that as documented in your letter dated November 3, 2014, you committed to providing documentation upon completion of hands-on patient cases for the use of the Sirtex delivery system. Please submit this information for Dr. Manzone in response to this request or in a future notification upon completion of the casework.

Please provide the above information either via a signed pdf or fax to my attention. Please reference Mail Control No. 609482 in your reply. If we do not receive a reply within 30 days, we will consider that you no longer require the requested additions and void your request. Please call with any questions.

Penny Lanzisera
Senior Health Physicist
U.S. NRC, Region I