

From: [Lanzisera, Penny](#)
To: [Wen, Carol](#)
Subject: Additional Information to Complete Amendment
Date: Tuesday, January 12, 2021 10:44:00 AM

Licensee: Christiana Care Health Services, Inc.
License No. 07-12153-02
Docket No. 03001303
Mail Control No. 624119

Dear Ms. Wen, in order to continue our review to add Dr. Helen Paik to your license as requested in the letter dated November 30, 2020, please submit the following additional information:

1. The preceptor attestation was signed by the Associate Program Director for Diagnostic Radiology who is also the Program Director for Interventional Radiology at the University of Pennsylvania. Please provide documentation from the Program Director to:
 - a. Confirm that Dr. Paik is able to independently fulfill the radiation safety-related duties as an authorized user for TheraSphere® and SIR-Spheres®;
 - b. Affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is a physician who is an authorized user for the type of Y-90 microsphere brachytherapy being authorized and concurs with the attestation provided by the residency program director.
2. Please provide the residency completion certificates for Dr. Paik for both Diagnostic Radiology and Interventional Radiology.
3. Please provide documentation to support that the TheraSphere® training provided by the manufacturer included:
 - a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - b. Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters;
 - c. Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject;
 - d. Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures. The procedures should address any special circumstances that may be encountered, such as the electrostatic charge of Y-90 microspheres and the proper survey instrument and survey technique for beta emitters.
4. Please provide documentation from both a SIR-Spheres® authorized user and a

TheraSphere® authorized user that Dr. Paik completed work experience or training under their supervision, including:

- a. Preparing and administering patient dosage. The individual does not have to be the physician who places the micro-catheter or administers patient dosage, but it is necessary that the individual have training in the administration process, including selection of activity of Y-90 microspheres to be administered to each treatment site and catheter positioning to ensure administration of the Y-90 microspheres is in accordance with the written directive; and
 - b. Using administrative controls to prevent a medical event involving the use of byproduct material; and
 - c. Evaluation of patient or research subject's treatments to determine whether the administered dosage was in accordance with the written directive or if a medical event has occurred.
5. Please submit documentation to support that Dr. Paik has successfully completed training in the operation of both the SIR-Spheres® and TheraSphere® delivery systems, TheraSphere® safety procedures, and TheraSphere® clinical use. This requirement may be satisfied by completing a training program provided by the respective vendor for new users or by receiving training supervised by an authorized user who is authorized for the type of Y-90 microsphere for which the individual is seeking authorization.
6. It appears from the letter submitted by the Residency Program Director at the University of Pennsylvania that Dr. Paik has completed several clinical cases for both SIR-Spheres® and TheraSphere®. Please provide documentation from both a SIR-Spheres® authorized user and a TheraSphere® authorized user confirming that the clinical use training, to support unsupervised use, included at least three hands-on patient cases for each type of Y-90 microsphere requested. Additionally confirm that the casework was conducted in the physical presence of the respective authorized user.
7. Please confirm if you are requesting authorization for 10 CFR 35.100, 10 CFR 35.200, or I-131 permitted by 10 CFR 35.300 for Dr. Paik as demonstrated by the forms submitted. If so, please clarify the supervising authorized users for training and casework completed from 2014 to when the current preceptor was authorized in 2017.

Please submit this information to my attention via email and refer to Mail Control No. 624119 in your reply. Please contact me with any questions. Thank you for your assistance,

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