

From: [Lanzisera, Penny](mailto:Lanzisera.Penny)
To: ruth.shanley@wchn.org
Subject: Request for Additional Information
Date: Tuesday, May 21, 2019 11:54:00 AM

Licensee: Danbury Hospital
License No.: 06-08544-01
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Dear Ms. Shanley, to continue our review of the request dated February 27, 2019, with additional information submitted May 13, 2019; please provide the following additional information:

1. Please confirm that the operating and emergency training provided to Mr. Wolthuis by Ms. Potari will include hands-on device operation, safety procedures, clinical use, and operation of the treatment planning system.
2. In your letter dated February 27, 2019, you indicated that you would adhere to NRC's guidance for Radioactive Seed Localization dated October 7, 2016, and submitted procedures in your letter dated May 13, 2019, to demonstrate this adoption. A review of your procedures identified a few discrepancies. Please confirm the following:
 - a. Radiologic Technologists involved in Radioactive Seed Localization procedures will be provided training in package receipt, routine monitoring, and emergency procedures commensurate with their duties and responsibilities.
 - b. Radiologists involved with implanting seeds will complete radiation safety training that includes: (i) identifying radioactive seed appearance, characteristics, radiation safety handling procedures and precautions; (ii) Utilizing the devices used to implant seeds (i.e., needles); (iii) Preparing a treatment plan; and (iv) Performing routine monitoring after all uses of the seeds to account for all seeds specified in the prescription and to ensure rapid identification and remediation of a damaged, ruptured, lost/missing or leaking source.
 - c. Any administration that results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from any of the following will be reported to NRC: (i) an administration of the RSL procedure using the wrong radionuclide; (ii) an administration of the RSL procedure to the wrong patient or human research subject; (iii) an administration of the RSL procedure using the wrong number of radioactive seeds; or (iv) a failure to perform the explantation surgery.
 - d. Medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g) will be implemented.
 - e. Surveys will be performed and records will be maintained as described in

§35.404 after explant of the seeds, including surveys of the operating room.

- f. Patients will be instructed in writing before implantation and agree in writing to return for removal of the radioactive seeds.

In addition, your instructions to pathology personnel for responding to a leaking/cut source and decontamination of personnel and the area instructs the pathology personnel to leave the room if possible. Please clarify if pathology personnel will survey their clothing, hands, and shoes and decontaminate prior to leaving the area.

You may submit the above information to my attention either via signed pdf sent to my email or via fax sent to 610-337-5269. If we do not receive a reply within 10 days, we will consider that you no longer need the requested amendment and void your request. Thank you for your assistance,

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