

DANBURY HOSPITAL

24 Hospital Ave
Danbury, CT 06810
203.739.7000
DanburyHospital.org

April 16, 2015

Ms. Penny Lanzisera
Senior Health Physicist
US Nuclear Regulatory Commission Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406

Licensee: Danbury Hospital

License # 06-08544-01

Dear Ms. Lanzisera,

These are the corrective actions and updating/retraining steps that we have taken since your visit:

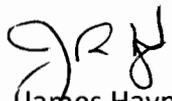
1. We reviewed all policies and edited them to include clarification concerning our response to failure of the patient to return for scheduled surgery. Step numbers 10 and 11 of the "Radioactive Seed Handling – For Localization of Breast Mass" tracking policy were part of this revision, and these revised copies were the ones that were submitted to you in February. The final revision date of February 16 was omitted from the copy that was sent to you.
2. Per your suggestion, we submitted a request for an amendment to remove the 5-day limit for the seeds to remain in place. While we still will schedule within 5 days, this would allow us to remain in compliance with our commitment to NRC guidelines in the event of a delay. This would be for unavoidable delays such as patient illness that occurs after medical clearance or weather-mediated cancellation of outpatient surgery.
3. We retrained the surgeon of the need to notify us if the patient's planned surgery is delayed for any reason. We retrained the surgeon's nurse scheduler in the following:
 - a. Seeds must not be scheduled more than 5 days prior to surgery. The breast center manager now gives the scheduler specific days on which seeds may be scheduled, i.e. "if surgery is scheduled for this day, you must schedule the seed on this day".

20150416 09:15 AM 006

- b. Patients who require medical clearance for surgery must be medically cleared prior to seed placement. We have had a test of this already; a patient's labs were not returned by the afternoon prior to the seed placement, and the scheduler let us know and cancelled the seed placement. Her labs returned, she was cleared, and we were able to reschedule her seed placement prior to her scheduled surgery.
 - c. Patients will not have seeds placed if they are awaiting genetic testing results. This only happened once, and the surgeon's office had already implemented this following that occurrence.
4. We have an additional surgeon who is starting to place seeds. In addition to his radiation safety training and delineation of his responsibilities re: notification, the Radiation Safety Coordinator met with his nurse scheduler to ensure that she understands and will follow the above.
5. The Radiation Safety Coordinator is now reviewing each scheduled patient for compliance with the 5—day scheduling. Since the end of January, we have placed seeds in an additional 27 patients, and all have been scheduled properly within the 5 days.
6. The Radiation Safety Coordinator is now monitoring the Seed Inventory Spreadsheet to ensure that all patients have returned for surgery by the specified time. The spreadsheet is now automatically flagging any seeds that are not returned to Nuclear Medicine within 5 days. If this occurs, the Coordinator and the RSO will investigate and calculate the dose using the spreadsheet created by the RSO. If the dose exceeds 50 cGy, it will be reported to the NRC promptly.
Since the end of January, all seeds have been returned on time.
7. We have decreased the activity of the seeds that we order from 0.15 mCi to 0.075 mCi. This will increase the number of days needed to reach the 50 cGy dose significantly, as well as decrease the 5-day dose for all patients.
8. We have begun an auditing process of written directives and other forms to ensure that all are filled out and to find any possible errors or omissions. An annual quality management procedure review will be performed by the radiation safety office to review statistics and seek possibilities for performance improvement initiatives.

We look forward to speaking with you, and welcome the opportunity to ensure that our Breast Seed Localization Program is in complete compliance with NRC guidelines.

Sincerely,



James Haynes

Vice President of Operations



Vladimir Monastyrenko, Ph.D.
Radiation Safety Officer
Danbury Hospital



Ruth Shanley, MS, RT(R), RDMS
Radiation Safety Coordinator
Western Connecticut Health Network