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March 31, 2017

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U.S. Nuclear Regulatory Commission
Region IV, 1600 East Lamar Blvd.
Arlington, Texas 76011-4511

Event Notification ID: #52614
Licensee Name: Siouxland Urology Center, LLC

Description of event

On the morning of March 16, 2017, an LDR brachytherapy prostate seed implant was performed at the Siouxland Urology Center (license ID# 40-34223-01). The procedure was a Palladium-103 implant, with a prescribed dose of 125 Gy. The implant was performed using Pd-103 seeds with an average activity of 1.68 mCi per seed. The prescribing physician was Dr. Gregory Naden.

This procedure was performed using intraoperative treatment planning. In this process, the oncologist and urologist take a series of trans-rectal ultrasound images, which determines a set of measurements regarding the size of the prostate, including the overall volume of the prostate. Using this data, the physicist makes a set of calculations which determines the number of seeds to be implanted, the number of needles to be used, the number of seeds per needle, etc.

According to the nomogram table used for this procedure, a total activity of approximately 135 mCi would have provided the prescribed dose to the given volume of the prostate. This activity would have been delivered by approximately 80 seeds. However, a different calculation was made, which led to the implant of 110 seeds, and a total activity of 184.8 mCi.

Dose information obtained in post-implant volume study

A post-implant volume study was performed on the patient on March 28, 12 days following the implant. During the patient visit a CT image was taken, and a volume study was performed using the Varian VariSeed treatment planning system. All implanted seeds were identified and located in the images.

The following dose information was obtained, and compared to suggested planning guidelines provided in the AAPM Task Group 137 report ("*AAPM recommendations on dose prescription and reporting methods for permanent interstitial brachytherapy for prostate cancer: Report of Task Group 137*"). Please note that these AAPM suggested values are ***not*** dose constraints for these organs, but are pre-planning goals.

PTV (Prostate)

D90% (minimum dose to 90% of the target volume):

- ***Planning goal***: at least 100% of prescribed dose
- ***Actual***: 157.81% of prescribed dose

V150% (% of target volume receiving 150% or more of the prescribed dose):

- ***Planning goal***: <50%
- ***Actual***: 91.69%

Rectum

D2cc (dose to the hottest 2cc of the rectum):

- ***Planning goal***: <100% of prescribed dose
- ***Actual***: 106% of prescribed dose

Urethra

The urethra could not be identified on the CT images, because a catheter was not used. Therefore, no dosimetric actuals could be obtained for this organ.

Notification of the patient

The patient was notified within 24 hours, and we continue to communicate with him and monitor him on a regular basis, as is discussed below.

Effect on the patient

In regards to the implant effect on the patient, we are hopeful there will be the usual side effects and nothing more. Almost every radioactive seed patient has problems with urination which includes frequency, urgency, a weaker stream, and some dysuria. This is quite common and it varies quite a bit. The patient is already on Flomax to improve his flow. We rarely see any rectal side effects from the implant. We also very rarely see any blood in either the urine or the stool.

The prescribing physician has kept in close touch with the patient, and he seems to be on the normal side effect profile. He is taking three Flomax a day to help improve his flow. He does get up at night, about every hour-and-a-half, for urination but is declining any anticholinergics.

A possible complication of too much radiation would be a fistula between the bladder and rectum. Another would be permanent obstruction of the urethra or damage of the urethra. Most cases of obstruction (which also happen with normal strength implants) are easily remedied by a Foley Catheter for a week or two. He still seems to pass his urine though, and is aware that he may need a catheter temporarily. From the looks of his CT dosimetry, it is doubtful that he would have any serious long-term side effects such as hematuria, rectal bleeding, permanent obstruction, or a fistula. This is something that we will be following very closely.

Why the event occurred

During this procedure, the physics calculations were performed in the operating room using two methods: an Excel spreadsheet, and a handwritten worksheet, which was hand-calculated. For this particular procedure, one of the values that should have been input into the spreadsheet (activity per seed) was never entered; instead, that cell of the spreadsheet contained data which was left over from the calculation of a previous implant. The calculations were carried through with this different data, and the calculation done on the handwritten worksheet also failed to uncover the differences. It wasn't until after all seeds had been implanted that a third review of the handwritten worksheet uncovered the differences.

A root cause analysis of this error reveals the following problems:

- A second independent verification of the input data being used in the physics calculations is not performed in the current process.
- This type of miscalculation would have been prevented had the calculations been initiated using a blank, 'template' spreadsheet, instead of a previously-used copy of the spreadsheet that contained other data.
- A more formal secondary calculation, designed to re-confirm the most critical calculation results, would greatly reduce the risk of differences going unnoticed.

Actions planned to prevent recurrence

1. We are introducing a new secondary hand-calculation, which is designed to use a different set of calculations to 'work backwards' to confirm that the original input values can be derived from the results produced by the original calculations.

2. Our formal procedure document is being revised to explicitly require that any calculations done by the physicist using the Excel spreadsheet must use the blank spreadsheet template as its starting point.

3. Following the successful secondary calculation, a verbal 'timeout' will be performed to confirm the input values used in the calculations. The following key parameters will be verified by cross-checking with independent sources in the room:
    - Prescription: cross-checked with Physician
    - Activity Per Seed: cross-checked with seed loading nurse
    - Volume: cross-checked with Nursing
    - Circumference: cross-checked with Nursing
    - Longitudinal Dimensions: cross-checked with Nursing

    Only after successful verification of these key parameters will the implant of seeds begin.

    This report is not an admission of liability.