

To: Wisconsin Pd-103 Registrants

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Subject: This information is being provided to you to assist you in reviewing your protocols for ordering and receiving Pd-103 and I-125.

Abstract:

Summary: An unintended activity strength of Pd-103 seeds was implanted into a patient due to the wrong units being used to order the seeds. The error resulted in a 29% increase from the planned activity strength.

The cause of the error was due to the fact that the activity strength of the Pd-103 seeds were planned with the new "U" units using the NIST WAFAC calibration, however, the seeds were ordered in "mCi apparent". The supplier assumed since the order was in mCi that it was based on the Cd-109 standard. The error was discovered because the facility keeps a post implant database and the activity strength was significantly different than other implants previously performed using Pd-103.

Detailed Discussion: The facility uses both I-125 and Pd-103 seeds for prostate cancer therapy. The treatment planning is done in air kerma activity strength (U) for both Pd-103 and I-125. Once the treatment plan is approved by the physician for implant, the seeds are ordered. Pd-103 seed activity strength is ordered in U. I-125 seed activity strength is manually converted and ordered in "mCi apparent". This is addressed in the facility's written procedures. The person ordering the material inadvertently converted the seed activity strength for the Pd-103 to "mCi apparent", contrary to the written procedure. By allowing the order to stand based on the Cd-109 standard, the source activity strength was increased by 29%. Upon receipt, 10% of the seeds were assayed according to the facility's procedures on a dose calibrator. However, this assay showed no discrepancy because the results from the dose calibrator are in mCi apparent and the individual checking would verify against the mCi apparent value which was stated on the order. The assay procedure did not use the treatment plan documents to verify the order, but used the fax-back order. In essence, the assay was verifying the calibration of the seeds instead of the activity strength of the treatment plan. In addition, the source strength was a familiar number for a prostate seed implant without external beam, although the treatment, in this case, was for a "boost", following treatment with external beam.

The facility discovered that the source strength used was out of range because they perform a post implant therapy review to assess how close they came to intended result and to track outcome. Essentially, a spreadsheet is used that shows all the treatment values and allows comparisons to be made between treatment plans. The goal is to give the acceptable minimum dose that produces the desired results. This has been difficult to track in the last two to three years due to changes in the NIST calibration factors. The company providing the Pd-103 seeds permits orders in either “mCi apparent” or “U” units so that the physician authorized users have a means to order the same dose/activity strength that has worked in previous treatments.

Lessons learned

The facility has analyzed the incident and has instituted the following actions:

- 1) The protocol for ordering seeds has been reviewed. The protocol states that I-125 seeds are ordered in “mCi apparent” while the Pd-103 seeds are ordered in “U”.
- 2) There is now a cross-check system in place for confirming seed orders. The faxed-back confirmation order is now reviewed by the medical physicist, instead of relying solely on the person who initially placed the seed order.
- 3) The procedure for verifying the seed activity on receipt has been modified to show all four values, (mCi and U based on Cd-109 standard and mCi and U based on new WAFAC standard), for activity strength so that the seed order activity strength is verified at the time of receipt. The treatment plan will also be available to confirm that the ordered and received seeds are compatible with the treatment plan.

In addition, the customer should confirm with the supplier which dose rate constant (i.e., Cd-109 or WAFAC) is programmed into the treatment planning software prior to changing its ordering procedures. In this incident, the facility had previously ordered in “U” units and then deviated from their standard practice by ordering in “mCi” units, which was not questioned by the supplier.