Radiation Oncology
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To: Andrea Browne, RSO; Rad. Onc. physics files

Subject: CHS I-125 seed implant on 8/29/2001 – final seed count off by one seed.

History:

Patient H. K. was scheduled for a I-125 seed implant at CHS on 8/29. The plan called for implantation of 103 seeds, at 0.327 mCi each, in 35 needles. As is customary for most implants, the required seed number was increased by 4 seeds as extras... just in case for an ordered total of 107. Seeds were ordered in the usual fashion from Mentor, our standard source for loose I-125 seeds, and received at CHS. As has been the practice, CHS nuclear medicine did both the intake survey and the seed assay and provided documentation to radiation oncology of such. At CHS, there is no initial count to determine that the stated and received quantities actually match.

On the day of surgery, either surgery staff gets the seeds from nuclear medicine or nuclear medicine delivers the seeds to surgery for sterilization. Sterilization is usually carried out be surgery staff, typically R.N.'s, who pour the seeds into a sterilization pig[1] and run the autoclave. The sterilization pig is placed in an open metal pan (typically with a perforated bottom covered by blue surgical towels to keep items from falling through) prior to autoclaving, but the autoclave is surveyed by the surgery staff afterwards with a meter provided by nuclear medicine. Such was the flow of events on 8/29. Finally, the Mentor calibration certificate was in agreement with Mentor's faxed order conformation as received at CHE in both quantity and activity.

Problem:

As the seed loading process wound down, I discovered the final count would be two seeds short of the four that should have been present. It should be noted that autoclaving tends to cause the seeds to stick together; so being off two seeds was a real possibility. Prior to patient implantation, the loading room, adjacent cysto. room, hallway, the O.R. in which the seeds were poured into the sterilization pig, the autoclave, and autoclave room were surveyed with a Ludlum 14c meter (sn:152790). No unusual readings were noted. Nurses Jennifer McCrocklin and Kelly Puckett poured the seeds into the sterilization pig on a wide and covered O.R. table, had no problems or saw anything amiss. Nurse Micky Mitchell surveyed the autoclave when she removed the seeds. The nuclear medicine tech (Terri) was notified of the problem, but the hotlab was not examined as it was time for surgery to start.

Unfortunately and fortunately, checks made during the procedure allowed Dr. M. Tharp to spot an early on loaded needle that contained 4 seeds instead of the planned for 3 (it measured 1 cm too long). The seed count was now off one seed.

After the case completed, all the above areas were resurveyed in considerably more detail. The O.R. room had not been used since the seeds were poured into the sterilization pig earlier in the day. Even the O.R. room on the other side of the autoclave room was carefully surveyed as a possible path. In nuclear

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medicine, Terri stated, that though busy, she carefully removed the three seeds assayed from the vial with tweezers rather than trying to pour several out of the vial. A careful survey of the hotlab turned up nothing. The hotlab survey was hampered by the materials being stored there and a minor work area contamination, but included the floor and items sitting on the floor (drug shipping containers, seed vial packaging, etc.). Nothing unusual was seen or measured.

Previously, the RSO (Dr. Browne) had been notified of the problem. On a subsequent conversation, she suggested a portable x-ray of the patient. This was done in the recovery area. A seed count on the resultant film easily yielded 100/101 seeds implanted (loading had been changed during surgery to conform to the prostate volume visualized at that time). One seed image looked extra large, probably due to two images almost superimposed; that would yield 101 seeds for the 101 implanted.

CHE has received 1 extra seed in each of two Mentor orders a long time ago. Though an unlikely possibility, Mentor was contacted on 8/30 regarding seed counts. In a follow-up call 9/4, I was told that their seed inventory had been right on. The only conclusion that can be drawn at this time is that if the correct number of seeds had been shipped, one remains unaccounted for. Per conversation with Dr. Browne, procedures will be revised at CHS (amongst them a vacuum pump for pre-counts has been ordered) and probably at other sites where seed implants are performed by CHI personnel.