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September 25, 2001

U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Dear Sir or Madam:

I am reporting the possible loss of radioactive material, an I-125 seed of 0.327 mCi activity. An incorrect post-procedure count indicated that a loss may have occurred. Since no verification count was preformed on the order prior to handling we are unable to substantiate if a loss did or did not occur. All surveys at post-handling steps were negative for radiation. A copy of the report compiled by the physicist performing the procedure is attached. In order to prevent future events the procedure for verifying and handling the seeds has been changed. A copy of the revised procedure is also attached. If any further information regarding this event becomes available I will forward it to you. If you have any questions, please contact me at the phone number listed above.

Sincerely,

Andrea D. Browne
Radiation Safety Officer

Printed on recycled paper.

SEP 28 2001

Radiation Oncology
Community Hospitals
Indianapolis

Carl Warner, Physicist
Radiation Oncology
Community Hospital - East
1500 N. Ritter Avenue
Indianapolis, Indiana 46219-3095
(317) 355-5347

4 September 2001

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

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.

NORTH AMERICAN SCIENTIFIC

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August 30th, 2001

Carl Warner
Com Hospital of IN South
1402 E. South County Line Rd
Indianapolis, IN 46227

Re: Discrepancy in number of I-125 seeds for order number 1016989.

Dear Mr. Warner,

This letter is in response to complaint forwarded to us by Mentor, on 8/30/2001. You stated in the complaint that you received 106 seeds from MBO6892K instead of 107 seeds as requested.

I am providing a description of our manufacturing process so that you can understand the techniques we used to investigate your complaints. As seeds are placed in our finished goods inventory, they are counted by an automated laser counting system and the batch counts are entered into our inventory database. Entries to and removals from the inventory database are individually verified for accuracy. When seeds are packaged for an order, they are counted by an automated redundant laser counting system. This system provides a high assurance of accuracy, allowing us to resolve a discrepancy of as small as one seed.

The investigation of your complaint regarding order # 1016989 found that the physical inventory for batch number MBO6892K matched the inventory database. The packaging room is routinely surveyed and there have been no incidents of loose sources in the counting room. For these reasons, we are unable to resolve the source of the discrepancy. I hope this helps in your efforts to conclude this matter. If I can be of further assistance regarding this matter, please contact me at (818) 734-8600

Sincerely,

Phuong Chau
Quality Assurance Assistant Manager

Radiation Oncology Community Hospitals Indianapolis

Carl Warner, Physicist
Radiation Oncology
Community Hospital - East
1500 N. Ritter Avenue
Indianapolis, Indiana 46219-3095
(317) 355-5347

11 September 2001

To: CHS Nuclear Medicine, CHS Surgery, CHI RSO, Rad. Onc. Physics/Dosimetry/files

Subject: change of procedure for seed implants.

The following procedure change may be considered fallout from the CHS I-125 seed implant on 8/29/2001. The final seed count was one short of the manufacturer-stated number of seeds (106/107). Search for this seed came up negative in the CHS surgery department, CHS nuclear medicine department, and in a post implant film of the patient. The vendor has stated that they had no inventory problems.

Procedure Change: count seeds in shipping vial to verify order quantity

To facilitate this, a vacuum tweezers with modified tip is being provided. Ten I-125 or Pd-103 will fit above the black (blue, red) line on the tip. This is periodically checked by actually counting the number of seeds between the lines. Little and very infrequent adjustments can be made by sliding the small inner tube in or out. Using the vacuum device, 120 seeds can be counted in five minutes or less. Seed counting has been standard operating procedure at CHE since the latter part of 1998 with only two orders to date incorrectly filled.

To minimize exposure, this can be done behind the L-block; seeds must be dry:

1. Dump vial's contents into some small and shallow container.
2. Place open and empty vial back in open pig.
3. Suck 10 seeds into tip, record count, dump tip's contents back into vial.
4. Repeat #3 till all seeds have been counted. You may wish to hold some seeds back for assay[1] at this time.

[1] Current recommendations call for assay of 10% of the order's quantity (10 out of 100 seeds).

Procedure Change: sterilization of seeds will be performed by radiation oncology staff

While there is absolutely no indication that any individual did something wrong or carelessly, in conversation with the RSO it has been decided to tighten procedures by limiting the number of staff handling seeds. A physicist or dosimetrist will retrieve the seeds from nuclear medicine, load and unload the autoclave, and transport the seeds to the needle loading area (usually the cysto. prep. room). The area where the sterilization pig is filled, the autoclave, and the needle loading area will be surveyed with an appropriate instrument. The needle loading area has been routinely surveyed all along. Basically, what is being implemented at CHS reflects the procedures in use for years at CHE. The one difference being that radiation oncology at CHE performs the initial seed count and assay rather than nuclear medicine.