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Message:

This is my 1st draft

any comments?

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To: Mr. Ronald Bellamy FAX 215-337-5269
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From: Melvin L. Griem,MD (former member ACMUI, USNRC)
Professor, Univ. of Chicago
FAX 312-702-2629
Ph 312-702-6883

Re: License # (not supplied) Wm. Backus Hosp. Norwich, CT

Phone consultations June 23, 1994

Contacts: - Above list of NRC staff + Conf. call 301-816-8100
Dr. Kenneth Roberts ph 203-785-2957, licensed user

Potential contacts:
Dr. Frank Friedman 203-886-1956, Urologist
Dr. Korshin, Medical Physics203-271-2624 or823-6303
Dr. Kimmett, Dosimetry 203-785-2955

Date: July 5, 1994

Signed:

SUMMARY:

A permanent Iodine 125 brachytherapy implant was done on June 22, 1994 by the medical team at the Wm. Backus Hospital (spelling?). 112 seeds were placed using ultrasound treatment planning and the Mick applicator technique in the prostate of a 70 year old patient. Source strength was 4.49 mc/ seed which was approximately 10 times the planned source strength. The usual dose for a permanent implant is approximately 160Gy The new estimated dose might have been as much as 10 times higher and well above tissue tolerance. The intent of the original treatment plan was to cure the tumor site without significant complications to surrounding organs.

DETAILS OF THE EVENT:

Using ultrasound pre-treatment evaluation the volume of tissue to be treated was planned and 0.43 to .046 mc seeds were ordered. On arrival from the supplier the dosimetrist noted that the seeds were 4.49 mc/seed and corrected that fact to 0.449 mc/seed in the isotope log book prior to the implant procedure. At about 10:30 AM on June 22, 1994 the procedure was started and completed about 12:30, implanting

112 seeds. On discovery of the problem, just following the implant, the prostate was resected removing over 60 seeds. One seed was transected and I-125 was found the patient's thyroid. Some 42 seeds remained in a plane in the perineum, in a plane in the anterior wall of the rectum and in the peri-prostatic tissue. A diverting colostomy was done to place the rectal tissue at rest. Orthogonal x-ray films at about 3:30 PM showed the above seed distribution and dose estimates were between 0.25 and 0.5 Gy per hour. (25 to 50 rads per hour).

I was contacted early on June 23, 1994 by NRC in Washington and contacted Region I for details. I then gathered information as above. I was instructed not to give any suggestions on management.

RECOMMENDATIONS;

Later in the day a conference call with NRC staff was arranged. I suggested that the patient be moved to Yale given the need to use complex imaging techniques to help localize and remove the remaining 42 seeds. Without removal a tissue dose of as much as 500 Gy or move might be expected from the remaining seeds which would cause necrosis of important tissues in the patient's pelvis. There was the high likelihood that a fistula to the perineum from the bowel or bladder could occur. I also suggested that Dr. Judith Stitt, of the current ACMUI, NRC and an attending physician at Univ. of Wisconsin, Madison be consulted. She has done extensive work with I-125 brachytherapy.

Although I have done extensive and original work with permanent interstitial brachytherapy, I have not used I-125 sources. On the other hand I have published extensively on the late effects of radiation.

On June 24, 1994, Dr. Stitt took over the medical consultation efforts in this interesting case and I gave her the details of the information I had collected. It is my understanding that on June 26, 1994 a major surgical procedure was done at Yale to remove the rest of the seeds.

ROOT CAUSE OF THE PROBLEM:

As with all permanent implants it is essential to check the activity of EACH source by some secondary means to verify the activity of EACH seed. When I did Radon seed implants in the 1950's using sources supplied by a supplier in Chicago who had a Radon plant it was essential to check EACH seed for activity. Some seeds leaked and had no activity and some seeds were not loaded to an equal activity. At that time I found that a calibrated GM counter was a convenient secondary device to check EACH seed just prior to insertion.

See: Quimby EH, Desjardins, AU.,Radon Seeds. JAMA 112:1822, 1939. about the use of Radon seeds. - nothing is really new about the need to check the activity of brachytherapy seeds as you do such a brachytherapy procedure.

Certainly part 35 of our NRC regulations SHOULD clearly state the need to check the activity of radioactive drugs and sources of THIS LEVEL OF ACTIVITY before use to spot errors in labels, calibrations etc.

SPECIAL NOTE:

I would appreciate receiving follow-up on this interesting situation.

I have not received any written correspondence from either NRC or from the licensee. As a result there may be spelling errors related to names and places in the above text. Please check and correct!