4/19/2013

To Whom It May Concern:

This letter is to report the occurrence of a medical event on 4/8/2013 at Saginaw Radiation Oncology Center in Saginaw MI. The patient was being treated via HDR with an Iridium-192 source of activity 8.4Ci (under the license # 21-01549-02, licensee: MidMichigan Medical Center) using a vaginal cylinder. On 4/9/2013 the physicist realized that the catheter length being used on the patient was not the appropriate catheter and was 4cm longer than it should have been. This meant that the treatment of 4/8/2013 was delivered approximately 4cm inferior to where it should have been. The plan was created with a catheter length of 116cm where as the catheter used, had a planning length of 120cm. The treatment was stopped upon realization, and upon consultation with the physician, Dr Paul G Kocheril, it was decided that the plan would be altered to make up for the mistreatment in two steps. One plan to adjust for the treatment on 4/8/2013 so as to push the dose superior to the correct location and to compensate for the inferior dose already administered, another plan to correct for the partial treatment on 4/9/2013. The patient was immediately notified upon realization of the medical event. It is in our opinion that the one day of mistreatment 4cm inferior will not be clinically relevant in terms of outcome or side effects due to our compensating for the missing dose.

A detailed review of the dosimetry of all plans summed together indicate the following:

Estimated dose to the vaginal wall at the prescription point (0.5 cm depth from the cylinder surface) at the last incorrect dwell position (most distal) was 525.9 cGy cumulative for the entire treatment. That same point was expected to receive 233.7 cGy from the intended treatment. No other tissues or organs received any substantial dose as a result of the error. The additional dose to the rectum was minimal.

The medical event occurred due to the catheter from a tandem mistakenly being used on the cylinder. The length of the catheter was measured and reported to the physicist, but was not recognized as being the wrong length during the second check process. Similar events will be prevented in the future by attaching a sticky label to each catheter with its intended applicator use. This will give everyone involved in the treatment a quick visual cue, in addition to measuring the catheter, as to the appropriateness of its use with the intended applicator. In addition a new time out checklist will be utilized for each fraction of treatment to ensure that the correct catheter length appears on the plan, the treatment report, and is recorded in the simulation sheet. Also there are sheets hanging around the HDR area that have listed all of the appropriate planning and measured lengths for each catheter when connected to the correct applicator. We believe that this was an oversight due to simple human error and is not part of any systematic problems with our policies and procedures as we have been quite successful in our HDR program at Saginaw Radiation Oncology Center for years without any issues.

If any other information is needed we may be contacted at 989-583-5250.

Sincerely

Ian B Reineck M.S. DABR