Jeppesen Radiation Oncology Center
A service of Bay Regional Medical Center
and MidMichigan Medical Center – Midland

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Licensee: Bay Regional Medical Center #21-1858501
Event #: 47384

Date of Medical Event: 05-19-2011 (Corrected copy)

Description of ME: : Patient planned and treated at Bay Regional Medical Center with a permanent I-125 seed implant to the prostate using an intra-operative planning approach. The plan was to treat the prostate to a dose of 140Gy. In the post implant review using CT the patient had a V100 value of 64.8%. This was deemed by the NRC to be an underdose of greater than 20%. Implant performed by Dr. J. F. Littles, MD.

Cause of ME: At the time of the implant we created a plan in the OR and evaluated it using the V100 value off of the Dose-Volume Histogram (DVH) prior to implanting the seeds. This V100 value was 99.2%.

We have verified that the seed strength used for planning agrees with that in the planning system. We have verified that upon leaving the OR, all seeds were accounted for and no seeds were recovered in the recovery room. The loading of needles was done by the physicist and a visual check of a fluoro film captured at the end of the procedure showed possibility of one seeds being in the bladder but it is not definitive. The foley balloon is intact in these images.

This leaves us with the possibility that the post-plan CT study is somehow not indicative of the actual plan. This CT was done14 days post implant and has a volume 47.4% larger than the intra-operative US volume. We feel strongly that this increase in volume, along with normal variability in drawing contours would certainly account for the smaller V100 value on the post-op study being

Patient Assessment: There has been no biochemical evidence of recurrent disease and side effects have been minimal. The referring physician and the patient have been notified.

Immediate Action to Prevent Medical Events: We currently have a stop on all seed implants until we are able to complete a new policy and procedure to provide high confidence that such events will not recur.

We are also intend to consider the use of stranded seeds to limit the small migrations that occur. Post implant CTs will be done at 4-6 weeks rather than 2-3 weeks so as to reduce the impact of edema. We are in the process of rewriting our policy and procedures,

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including the Written Directive and prescribing method so as to make the implanted activity the regulatory criterion of dose delivered. We are also looking at all steps of the implant process to insure that no step introduces the possibility of human errors.

Re: Implementation of immediate and long-term corrective actions to maintain and implement written procedures to provide high confidence that the I-125 prostate implants are done in accordance with the written directives and the associated treatment plans.

Our corrective actions to address the above statement by the NRC will involve three primary changes. These include:

1. A complete revision of the Policies and Procedures for performing prostate seed implants at Bay Regional Medical Center.

2. A revision of our written directive format so as to make clear that we will be prescribing the dose to be delivered in terms of the total source strength and exposure time.

3. A policy that involves a procedure of consistent review of implant procedures and documentation to both insure regulatory compliance as well as insuring quality clinical procedures.

At the present time, we have taken the prior (outdated) Policy and Procedure document and noted outdated and/or irrelevant items as well as items that we intend to add and are well along in the initial process of completely rewriting it. Due to its importance, this is not being rushed. The Physics and Medical staff are making these changes and should complete them within a week. At that point it must go to the hospital for further review and clarification before it receives final approval.

The second implementation mentioned above involves taking our current two-page Written Directive and Quality Management Checklist and rewriting it to more clearly separate the actual written directive and oral revision portion from the remainder that deals primarily with needed record keeping. It was ordered chronologically so as to start with a prescription, moving on to pre-implant source strength verification; then the actual implant data and finally various radiation safety surveys. This was convenient for not missing items but we will probably separate it into a prescription/revision/ implementation portion and a separate part on surveys/assays etc. – in a sense, separating some of the physics aspects from the clinical portion.

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As mentioned above, we will be changing our method of dose reporting for purposes of identifying medical events more accurately. We will be following the recommendations of the working Group of the *American Society for Radiation Oncology* by using total source strength as this is an alternative dose definition presented in NRC documents. We hope that this will allow us to identify future medical events without using the clinical outcome parameters often presented in brachytherapy literature.

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