

353 Fairmont Boulevard Rapid City, SD 57701 (605) 719-2300 FAX (605) 719-2310

April 15, 2013

U.S. Nuclear Regulatory Commission ATTN: Regional Administrator 612 E. Lamar Blvd., Suite 400 Arlington, TX 76011-4125

Summary report for Rapid City Regional Hospital LDR brachytherapy medical event, February 26, 2013

Licensee Name: Rapid City Regional Hospital

License Number: 40-00238-04

Physician Name: Daniel Petereit, MD

On April 2, 2013 at approximately 8:00 AM it was discovered that a patient who was prescribed a dose of 110Gy, to the prostate, received a dose of 145Gy. The difference between the prescribed and the delivered is 31.8%. In accordance with Nuclear Regulatory Commission: 10 CFR 35.3045(a)(1)(i), this is a medical event. The event was reported to the Nuclear Regulatory Commission April 2, 2013 at 12:50PM (MST), event # 48876.

The written directive was written for the prostate to receive 110Gy. The treatment planning system had been programmed to default to 145Gy. This number was not changed when the plan was created. The implant was performed on February 26, 2013. The mistake was discovered when the post plan dosimetry was performed April 2, 2013. At that time the appropriate notifications were made to the patient, referring physician and the Nuclear Regulatory Commission.

As a result of this incident we have reviewed previous charts, to verify this was an isolated incident. We will be reviewing and updating our brachytherapy policies. We will add two physics checklists to the prostate seed implant patient workbook. One will be for the planning physicist and the other for the reviewing physicist. A physician checklist will also be created. These documents will require approval and will be stored in the patient's electronic medical record. We will also be changing the default settings in the treatment planning computer so the dose will be manually entered each time.

Time-out procedures in the operating room will be changed. Currently in the Operating Room the time-out consists of patient name and the procedure being performed. The time-out will now include the verification of the dose being delivered to the patient.

An initial root cause analysis involving the hospital Risk Management Department was conducted on April 3, 2013. There will be a more in depth root cause analysis performed by Cancer Care Institute leadership and the primary individuals involved in which an action plan will be developed to address the findings of that procedure. The timeline of events moving forward are as follows: Root Cause Analysis completed by May 3rd, action plan developed by May 24th, and completion of items identified in the action plan by June 24th, rollout and training of new policies and procedures by July 24th.

The final results of our in depth analysis will be provided by May 3, 2013.

Timothy Sughrue

Chief Executive Office

Rapid City Regional Hospital

605-719-8162

tsughrue@regionalhealth.com