



6/26/18, 2018

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

Licensee Name: Rapid City Regional Hospital

License Number: 40-00238-04

Response to letter received June 7, 2018

On March 8, 2018 and March 12, 2018 the patient was treated with the incorrect setup. On March 15, 2018 the patient was treated with the correct setup. Following the third treatment, both physicists were in the HDR. The patient's setup was still on the treatment table, the physicist who had delivered the first two treatments noticed the accuform in the setup. At this time the patient had already left the facility. His next treatment was scheduled for March 19, 2018. This was discussed with the physician and the decision was made to perform a CT without the accuform, prior to the next treatment. The plan was recreated, using the same dwell weights and positions as the original plan. At this point we discovered that the patient had been under dosed by more than 50%. Physics notified the NRC and the authorized user (prescribing physician). The authorized user then notified the referring physician.

The authorized user states that in his medical opinion the patient is very unlikely to have an adverse reaction, since this was an under dose.

As a result of the misadministration discovered March 19, 2018 a root cause analysis was performed. The direct cause of the incident was the failure to properly recreate the initial patient setup. The exclusion of the accuform caused the patient's head to be in the wrong position, leaving a gap between the treatment device and the patient's skin.

Contributing factors include the lack of a specific policy regarding custom immobilization in HDR procedures, this was only the second brachy patient using custom immobilization, the pictures from the simulation did not completely show the accuform, and it is generally a therapist, not a physicist, who reproduces the daily setup using custom immobilization.

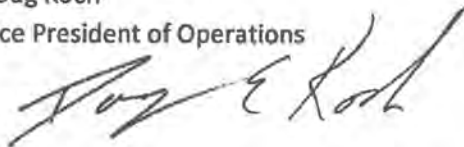
Action Item	Items identified during root cause analysis	Corrective action
1	At the time of treatment, there was not a policy specifically written for skin brachytherapy	A policy was created and provided to Michelle Simmons on April 4, 2018
2	The accuform was not used in the patient setup	Our new policy ensures that a therapist will be present at the first treatment, any time a physicist is treating the patient for the first time, and available for any subsequent treatment.
3	The pictures from the simulation did not completely show the custom setup.	In the CT simulation any custom immobilization, used in brachytherapy, will be photographed with and without the patient. This will ensure that each piece of the custom device can be clearly visualized.
		Our IT department has installed a computer monitor, keyboard, and mouse in the HDR treatment vault. This will allow the verification of the setup notes and photographs in the treatment room.
4	At the time of the incident there was not a verification system in place, to track the items needed for each custom setup.	Physics has worked with the IT department and Elekta to implement a bar code scanning system, to track custom setup devices.*

\*I have included with this letter a list of devices which we can currently create bar codes for.

James Mckee  
Medical Physicist, RSO  
Rapid City Regional Hospital



Doug Koch  
Vice President of Operations



Device_ID	Description
Accuform	Custom Headrest
Angled Board 10	Breast Brd Angled 10
Angled Board 15	Breast Brd Angle 15
Angled Board 20	Breast Brd Angled 20
Bellyboard - A	Bellyboard - A
Bellyboard - B	Bellyboard - B
Bellyboard - C	Bellyboard - C
Bite Block	Bite Block
Bolus 0.5	Bolus 0.5
Bolus 1.0	Bolus 1.0
Bolus 1.5	Bolus 1.5
Bolus Custom	Bolus Custom
Bolus Metal	Bolus Metal
Head Rest A	Head Rest A
Head Rest B	Head Rest B
Head Rest C	Head Rest C
Head Rest F	Head Rest F
Lead Shield Cust	Custom Lead Shielding for Electrons
Mask - S-Frame	Mask - S-Frame
Mask- Aquaplast	Mask- Aquaplast
O-Ring	O-Ring
Prone Head Spt	Prone Head Support
Pull Ropes	Pull Ropes
Knee Sponge	Knee Sponge
Triangle Sponge	Triangle Sponge
Angled Head Holder	Angled Head Holder
Blue Prone Sponge	Blue Prone Sponge
Riser-Knee Spong	Riser-Knee Sponge
SBRT Board	SBRT Board
SRS Frame - BRW	SRS Frame - BRW
VacLoc	VacLoc
Wingboard	Wingboard