Beaumont

Beaumont Hospital - Farmington Hills
28050 Grand River Ave.
Farmington Hills, MI 48336-5933

March 30, 2016

Beaumont Farmington Hills (formerly Botsford General Hospital)
Beaumont Cancer Center, Farmington Hills (formerly Botsford Cancer Center)
28050 Grand River Avenue
Farmington Hills, MI 48336

U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

SUBJECT: Report and Notification of a Medical Event (10 CFR Part 35.3045 Subpart M – Reports) Re: **Event No. 51796**

NRC License No. 21-08892-01

Licensee's Name: Beaumont Farmington Hills, the HDR is situated at Beaumont Cancer Center, Farmington Hills

Name of the prescribing physician: James Fontanesi, MD, Radiation Oncologist (AU)

A brief description of the event follows:

A reportable item, as regulated by 10 CFR Part 35.3045 (a)(1)(iii) The fractionated doses delivered differs from the prescribed dose, for a single fraction, by 50 percent or more was identified on March 16, 2016 when our Elekta (formerly Nucletron) HDR Microselectron malfunctioned as follows.

A patient was under spinal anesthesia for a treatment to the prostate to a prescribed dose of 13.5 Gy for the 2nd fraction. The patient was previously treated to 13.5 Gy to the prostate for Fraction #1, 2 weeks earlier without any issue.

The plan at Fraction 2 following our written directive of real-time planning based on the ultrasound acquisition that day called for 19 interstitial catheters to the 30 cc prostate gland. The V100 of the prostate was expected to be 99.75% (100% dose of 13.5 Gy covered 99.75% of the prostate volume). All coverage and critical organ sparing criteria were met and the physician approved the plan.

However during treatment and after completion of 9 catheters the treatment console reported an error (and subsequently retracted the source during the 3rd dwell position of the 10th catheter). The error code 9 message was source has moved from dwell position and a reset of the treatment console was required.

The event occurred as a result of Machine Malfunction.

The AMP and AU noticed the error on the console and determined that the source did retract to within the afterloader safe. The AMP went inside the treatment room with the survey meter to ensure the source indeed retracted. The AMP ensured that the transfer tube and applicator appropriately connected, which they were as was the case prior to initiation of the patient treatment. Attempts were done to continue with the treatment as error code direction was: cancel the error and try again.

However, the afterloader would not resume treatment and the treatment console reported error code 117 error during check out-drive in channel (driving out the check cable).

Several attempts were made with help of Elekta Field Service representative on the phone and also their National phone support to troubleshoot the issue as the message on the treatment console with these errors is that if the problem persists, contact your local Elekta Service representative. Troubleshooting continued afterwards with a Field Service Engineer coming on-site. We were later informed by the engineer that parts had to be ordered to resolve the issue and that they would arrive early the next morning.

The procedure was eventually terminated due to the malfunction service issue and patient was sent to recovery and family informed.

The approximate dose delivered was assessed using the treatment console generated post-treatment report, which indicated exactly how many seconds of the planned treatment was given, along with the corresponding catheters and dwell positions.

The total treatment time called for 386.6 seconds. with an activity of the source being 10.453 Ci at the time of treatment. However only 160.2 s of the planned treatment was delivered based on the Post Treatment Report. We determined retrospectively (the AMP and dosimetrist) on the Oncentra Prostate treatment planning system using the catheters and dwell positions and time (158.5 s) of the fully completed catheters and dwell positions was delivered correctly. 1.7 s out of 2 s of the third dwell position of the 10th catheter was also delivered but not accounted in the following dose reconstruction.

The v100 to the prostate is showing as 12.52% (100% of the dose of 13.5 Gy covered only 12.52% of the prostate volume) of the partially treated procedure. This represents an underdose to the treated volume. There was no excessive dose anywhere I.e. to critical structures that we use during treatment planning of urethra and rectum. The table below highlights what was planned and delivered, with our planning goals and whether they were achieved (yes/no) as part of the treatment plan.

Treatment Volume (cc): **Prostate** (29.97619 cm^3)	Goal/(yes/no)	Planned	Delivered
V100 (volume of 13.50 Gy as % of gland size)	> 98% (yes)	99.75%	12.52%
V150 (volume of 20.25 Gy as % of gland size)	< 30% (yes)	22.45%	2.54%
V125 (volume of 16.88 Gy as % of gland size)	< 60% (yes)	59.20%	5.23%
Organ at Risk-OAR (cc): **Urethra** (1.08311 cm^3)	Goal/(yes/no)	Planned	Delivered
D1 cc (dose as % of 13.5 Gy to 1cc)	< 115% (yes)	114.75%	48.69%
V100 (volume of 13.50 Gy as % of gland size)	< 90% (yes)	86.62%	0.0%
V115 (volume of 15.53 Gy as % of gland size)		0.65%	0.0%
Organ at Risk-OAR : **Rectum** (Max dose point)	Goal/(yes/no)	Planned	Delivered
Dmax (max dose as % of 13.5 Gy)	< 75% (yes)	74.59%	51.53%
V100 (volume of 13.50 Gy as % of gland size)		0.0%	0.0%
V75 (volume of 10.13 Gy as % of gland size)		0.0%	0.0%

The effect on the patient who received the administration is that there was an underdose during the planned treatment and that the treatment will be given again in a few weeks time to complete the course of Radiation Therapy via HDR Prostate Brachytherapy with a dose yet to be determined.

The actions taken and planned to prevent recurrence:

There was no indication of malfunction on the prior to treatment daily QA of that day. Also all prior treatments to any site, not just our prostate treatments did not have a malfunction of this type. The service was completed 03/17/16 per the vendors Field Service Report. A copy is attached. QA was done and the machine cleared for further treatment. There was no reason to suspect that the malfunction was not resolved. A patient (Ring and Tandem case) was treated successfully on 03/18/16.

In summary, we receive indication from vendor authorized FSE that the machine is cleared for clinical treatment pending our own QA. We implement the QA to test functionality and each morning of scheduled HDR treatment during the day, daily QA is done and reviewed by the AMP. Should there be intermittent issues indicating lack of acceptable functionality, we will contact the manufacturer to indicate the nature of the problem and gain their certification that the unit is cleared for clinical use, otherwise we will post-pone all HDR treatments and report the nature of the issues as appropriate.

We certify that as a licensee the patient and responsible relative were notified. This is documented in our records with an On Tx Notes. The electronic note is done for each brachytherapy administration and in this case also highlights how the AU saw the events unfold. Annotated with a copy of this report is the individuals name and SSN.

Briefly, the patients' family was immediately notified that there may be a delay with the procedure as attempts were underway to resolve the issue. Later it was determined to abandon the procedure with only partial treatment being delivered. At no time was there any evidence that the HDR source caused any exposure to personnel or extra radiation to the patient as it was documented to be in its home safe. The family was notified of the decision and given ample opportunity to ask questions which they did. Patient had all catheters removed by the AU without incident and then transported to recover at the hospital. Patient was contacted the following day on 03/17/16 and was in good spirits and understood issues of machine malfunction and the need to repeat the procedure in about 2 weeks. The referring physician, Urologist Dr. William Johnston was notified.

Sincerely,

Misbah Gulam

Misbah Gulam, MSc, DABR, AMP
Medical Physicist
21st Century Oncology
Beaumont Cancer Center, Farmington Hills
27900 Grand River Avenue
Farmington Hills, MI 48336
248-473-4802

Dr. Timothy McKnight

Timothy McKnight, DO
Radiation Safety Officer
Beaumont Cancer Center, Farmington Hills
28050 Grand River Avenue
Farmington Hills, MI 48336
248-471-8120

cc Dr. James Fontanesi, MD

Dr. William K. Johnston III, MD

David Gaffney, Vice President, Imaging and Lab

Laurel Jackson, Director, Beaumont Cancer Center, Farmington Hills

Keenan Brown, Elekta FSE

David Olmsted, Elekta FSE

ELEKTA

Work Order Number:
WO-01432488

Parent Case: 02164895

Service Report

Customer Information	Machine & Contact Information		Visit Information
Beaumont Health - Farmington Hills **Customer Number:** 13398 **Service Contract:** SM00037663 **Address:** 28050 GRAND RIVER AVE FARMINGTON HILLS, MI 48336-5933	**Model:**	MICRO SELECTRON V3, 18CH ENGLI	**Engineer:** Keenan Borg keenan.borg@elekta.com **Service Manager:** Jay Daley jay.daley@elekta.com **Job Type:** Service **Order Date:** 3/16/2016
	Location:	BOTSFORD HOSPITAL/CANCER CLINIC_Radiation Oncology	
	Serial No:	10322	
	Software Version:	3.1.5.	
	Purchase Number:		
	Contact Name:	Vickie Williams	
	Phone Number:	(248) 471-8120	

Reason for Service	
As reported/requested by customer:	**Initial assessment by Elekta:**
Error code 9 received while treating on HDR unit - patient on table *Error code 117 when attempting to resume treatment.* *Vickie Williams @ 248-471-8120*	*Error code 9 received while treating on HDR unit - patient on table*

Actions Performed:
Replaced v-block and opto-pair. Tested numerous times w/out failure. Tested QA plan that had previously failed successfully.

Item no	Description	Quantity	Start Date/Time	End Date/Time
	200 Travel Standard Rate	1	3/16/2016 3:00 PM	3/16/2016 4:00 PM
	100 Labor Standard Rate	1	3/16/2016 4:00 PM	3/16/2016 5:00 PM
	110 Labor OT Rate	2	3/16/2016 5:00 PM	3/16/2016 7:00 PM
	210 Travel OT Rate	1	3/16/2016 7:00 PM	3/16/2016 8:00 PM
	200 Travel Standard Rate	1	3/17/2016 8:30 AM	3/17/2016 9:30 AM
	100 Labor Standard Rate	4	3/17/2016 9:30 AM	3/17/2016 1:30 PM
	200 Travel Standard Rate	1	3/17/2016 1:30 PM	3/17/2016 2:30 PM

The equipment has been serviced in accordance with the Service Agreement between customer and Elekta and/or the Service Order request (as applicable). At the time of conclusion of the service performed, the equipment was technically operational. The customer is responsible for ascertaining that the equipment is ready for clinical use.

Machine Status: Operational

Elekta Engineer Signature: Customer Signature:

Elekta, Inc. * 400 Perimeter Center Terrace * Suite 50 * Atlanta, GA 30346 USA

Beaumont

MEMORANDUM OF UNDERSTANDING BETWEEN THE RADIATION SAFETY OFFICER AND RADIATION SAFETY OFFICER DESIGNATE

The Radiation Safety Officer, Timothy Allen McKnight, DO, is responsible for ensuring 1) the establishment and execution of the Radiation Safety Program, 2) compliance with all Federal and State rules and regulations regarding ionizing radiation, 3) maintenance of the Nuclear Regulatory Commission license, and 4) development of programs or resolution of problems involving radiation safety related matters.

The Radiation Safety Officer in the endeavor to accomplish these responsibilities requests the cooperation and assistance of the authorized medical physicist for radiation oncology services, who is under contract with Beaumont Hospital – Farmington Hills. The authorized medical physicist providing radiation oncology services is qualified, as described in Title 10 of the Code of Federal Regulations, Part 35, and is hereby named as a Radiation Safety Officer Designate for radiation oncology services. The RSO Designate agrees to follow the established policy "DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER DESIGNATE." Both the administrative representative and the RSO for Beaumont Hospital – Farmington Hills agree that the individual listed below may serve as a Radiation Safety Officer Designate for radiation oncology. FMRT administration also agrees that the individual listed below may serve as a Radiation Safety Officer Designate for radiation oncology at Beaumont Hospital – Farmington Hills.

03/30/16

Misbah Gulam, MSc, DABR — Date
Radiation Safety Officer Designate
Cancer Center-Beaumont Farmington Hills

3/30/16

David J. Gaffney — Date
Vice President, Imaging and Lab
Beaumont Hospital – Farmington Hills

3/30/16

Timothy Allen McKnight, DO — Date
Radiation Safety Officer
Beaumont Hospital – Farmington Hills

3/29/16

Jeffrey Margolis, MD — Date
Chief Executive Officer, FMRT

U.S. NRC License Number 21-08892-01
State of Michigan Facility Registration Certificate

Beaumont

DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER DESIGNATES

The Radiation Safety Officer (RSO) is assisted by the Radiation Safety Officer Designate (RSOD) in the radiation oncology department at Beaumont Hospital – Farmington Hills.

The Radiation Safety Officer Designate:

1. Is expected to sign a Memorandum of Understanding with concurrence from the Beaumont Hospital – Farmington Hills administration, the Radiation Safety Officer, and administrative representative for FMRT. This memo will be kept on file for review by the Nuclear Regulatory Commission.

2. Has the authority to stop an activity involving ionizing radiation and/or radioactive material in the radiation oncology department that pose a threat to the health and safety of any employee, staff, visitor, or patient. If such action is taken, it must be reported immediately to the RSO.

4. Is expected to ensure that all policies and procedures involving ionizing radiation and radioactive material used in radiation oncology are followed and is expected to alert the RSO of changes needed in policies, procedures and reviews of pertinent information regarding the radiation safety program.

5. Is expected to report verbally, by memo or e-mail any variances from defined policy, procedures, license agreement, federal, law, state rules and regulations he or she is aware of to the RSO.

6. Is expected to participate in quarterly Radiation Safety Meetings and report necessary Quality Assurance data.

Botsford Health Care
Fax Cover Sheet

☒ Botsford Hospital ☐ Botsford Clinics
☐ Community EMS ☐ Botsford Continuing Care Corporation

Date: 3/30/2016

Please deliver the following page(s) to:

Name: Colleen Carol Casey Dept./Company: NRC-licensing reviewer

Phone: 630-829-9841 Fax: 630-515-1078

Number of pages sent (including this page): 8

If you do not receive all the pages, please call.

From:

Name: Sandra Adkins CNMT

Dept/Clinic: Nuclear Medicine

Address: Beaumont Farmington Hills(formerly Bots

28050 Grand River Avenue

Farmington Hills Mi 48336

Phone: 248-471-8391

Fax:

Comments:

HARD COPY TO FOLLOW

8-2-07
*A8060044