MEDICAL CONSULTANT REPORT (SHORT FORM)
(To be completed by medical consultant, if site visit is not necessary)

Medical Consultant Name: Subir Nag, MD **Report Date:** April 19, 2018

Signature: Subir Nag

Licensee's Name: Missouri Baptist Medical Center

License No. 24-11128-02 **Docket No.:** 030-08325

Facility Name: Missouri Baptist Medical Center **Incident Date:** 1/29/2018

Estimated Dose to Individual or Target Organ: 190 cGy

Probable Error Associated with Estimation: Minimal

Prescribed Dose (Medical Event Only): 340 cGy per fx x 10 = 3400 cGy total

Method Used to Calculate Dose: Treatment Planning Computer

General Description of Records Reviewed: Incident report, Consultation Note, Follow up notes, Dose prescription and intended dosimetry, Dosimetry of actual dose delivered, and Corrective actions taken.

Individuals contacted during investigation: Thomas Moenster, RSO, Pawel Dyk, MD, AU.

Description of Incident: A patient of breast cancer was to receive a planned 340 cGy per fx x 10 = 3400 cGy HDR brachytherapy using a SAVI applicator with 7 struts. After the first treatment (340 Gy planned), it was discovered that catheter nos. 2 and 6 were mislabeled, resulting in the skin getting a higher dose (850 cGy to 1 cc volume) and the target volume receiving a lower than intended dose (56% of prescribed to 90% of target). The remaining nine treatments were cancelled, and the SAVI applicator was removed.

Consultant's Opinion:

1. This is a medical event due to both (a) excessive dose to the skin (850cGy to 1 cc of skin) and (b) lower than intended dose to the target (56% to 90% of target) for the first fraction. The treatments were stopped after 1 of 10 planned fractions. This will minimize any expected adverse reaction since the total dose received (850cGy to 1 cc of skin) is less than the total maximum cumulative dose from all ten treatments that the skin should not have exceeded (3740cGy). The target has received lower than intended dose to the target (only 5.6% of the intended dose for all fractions). Hence the local treatment is considered to be medically incomplete and patient is at risk for local recurrence.
2. The licensee has reported the medical event to NRC on Feb 8, 2018.
3. The licensee has notified the referring physician and patient.
4. The licensee has performed a root cause analysis and has taken appropriate corrective actions including revising the HDR policy and procedures for identifying and verifying catheter struts and retraining pertinent staff.
5. There has been no adverse acute skin reaction or recurrence noted thus far (at 2 months). I do not expect any acute skin reaction after this time, but there is still a small risk for late toxicity (subcutaneous fibrosis, scarring). The target has received lower than the intended dose hence patient is at risk for tumor recurrence. The patient will be receiving Arimidex (a hormone based therapy) as an alternate tumor therapy. The radiation oncologist will continue to monitor the patient for toxicity and recurrence. Further oncologic intervention (surgery) will be considered if there is a recurrence.
6. Based on my review I agree with the licensee's written report that was submitted to the Nuclear Regulatory Commission (NRC) in the following areas:
    a. Why the event occurred

b. Effect on the patient
c. Licensee's immediate action on discovery
d. Corrective actions taken to prevent recurrence

Why Site Visit is Not Required:

1. The description and cause of the adverse event are clear.
2. I have talked with the individuals involved in the case, reviewed the medical and dosimetric information on this patient and confirmed that the licensee has taken the appropriate corrective actions.
3. The licensee has informed the appropriate persons/officials.

Assessment of probable deterministic effects of the radiation exposure on the individual:
There has been no adverse acute skin reaction or recurrence noted thus far (at 2 months). I do not expect any acute skin reaction after this time, but there is still a small risk for late toxicity (subcutaneous fibrosis, scarring). The target has received lower than the intended dose hence patient is at risk for tumor recurrence. The patient will be receiving Arimidex (a hormone based therapy) as an alternate tumor therapy. The radiation oncologist will continue to monitor the patient for toxicity and recurrence. Further oncologic intervention (surgery) will be considered if there is a recurrence.

Thank you,

Edward Harvey

Health Physicist

US NRC Region III

Division of Nuclear Materials Safety

(630) 829-9819

From: Subir Nag [mailto:nagsubir@gmail.com]
Sent: Tuesday, April 17, 2018 6:22 PM
To: Harvey, Edward <Edward.Harvey@nrc.gov>
Cc: Subir Nag <nagsubir@gmail.com>
Subject: [External_Sender] Medical Consultant Report of Medical Event

Hello Edward:

I am enclosing my preliminary report of the medical event at Missouri Baptist Hospital. Kindly do not hesitate to contact me if you require any clarifications.

Subir

Subir Nag, MD

Consultant Brachytherapist

12637 Star Ridge Court

Saratoga, CA 95070

650 305 6622

nagsubir@gmail.com

From: Subir Nag
To: Harvey, Edward
Cc: Subir Nag
Subject: [External_Sender] Fwd: Medical Consultant Report of Medical Event
Date: Thursday, April 19, 2018 11:17:55 AM
Attachments: 1NRC ME Mo Baptist v2 Apr2018.doc

Hello Edward:
I have clarified my report to include my opinion regarding any deterministic effects and the medical or biological significance given the actual exposures. Kindly do not hesitate to contact me if you require further clarifications.
Subir

Subir Nag, MD
Consultant Brachytherapist
12637 Star Ridge Court
Saratoga, CA 95070
650 305 6622
nagsubir@gmail.com

On Wed, Apr 18, 2018 at 3:18 AM, Harvey, Edward <Edward.Harvey@nrc.gov> wrote:

> Dr. Nag,
>
> Thank you for providing a timely review of the information you received yesterday and for sending the preliminary report. After reviewing your report, I noted two items that need clarification.
>
> The first clarification needed is under the "Assessment of Probable Deterministic Effects" section. You state that there have been no deterministic effects observed. However, could you also please provide, based on your professional opinion, whether or not you anticipate any deterministic effects given the actual exposures?
>
> Also, under the Charter, we requested that you gather information regarding the dose actually received by the patient as compared to the prescribed dose to determine if the medical event was medically or biologically significant. I see that you included the dose information, but I do not see any statements referring to the medical or biological significance. Would you be able to include something to this effect?
>
> Please do not hesitate to contact me with any questions.