Medical Consultant Report

Medical Consultant: Douglas Einstein MD PhD

Report Date:

Signature: _____

Licensee Name: Henry Ford Macomb Hospital

Licensee Number: 21-11850-01

Docket Number: 030-02106

Incident Date: Multiple; report date 12/10/2010

Individual Physician/Physicist Names:

Authorized User Radiation Oncologist: Jandranka Dragovic, MD and Ibrahim Aref, MD

Authorized Medical Physicist: Brett Miller

Radiation Safety Officer: Khurram Rashid, MD

RECORDS REVIEWED:

1) Preliminary Description of Incident Form from NRC
2) Copies of CT Slice Images and Dosimetry from Brett Miller via Email Requested 2/16/11 and received on 2/21/11
3) Review of patient follow-up notes to assess current medical condition of patients requested 2/21/11 and received 3/2/11
4) Discussion with the AMP Brett Miller 3/7/11 and request for further detailed dosimetry
5) Review of detailed dosimetry received 3/8/11
6) Discussion with the treating radiation oncologist Dr. Dragovic 3/22/11

Prescribed and Estimated Dose to Individual or Target Organ:

From Data Prepared and Calculated by Brett Miller, AMP of Licensee

The Equivalent Dose in 2 Gy fractions was calculated based on the American Brachytherapy Society accepted formulas (Nag, et al IJROBP 46(2):507-513, 2000)

Per AMP:

1) **Per the AMP, All doses were prescribed to the surface with a treatment length prescribed of 4cm using a 16 cm vaginal cylinder applicator.**
    a. **Therefore per discussions with the AMP, given the 4cm prescription length and the 16 cm vaginal cylinder, the vaginal cylinder did provide distance separation between the source and the tissue throughout the entire length of 4cm prescription length with the exception of the margin of less than 1cm at the most distal end of the cylinder.**
2) **The "Superficial dose" was the average dose calculated by the AMP in a rind volume of tissue from the skin surface to 3mm depth covering the entire CT volume of tissue up to the 0.5 Gy isodose line, including tissue at a distance > 3cm of the source.**
3) **The "Deep dose" was the average dose calculated by the AMP in a rind volume of tissue from the skin surface to 3mm depth to 7mm depth from the skin surface covering the entire CT volume of tissue up to the 0.5 Gy isodose line, including tissue at a distance > 3cm of the source.**

4) Since the acute tissue effects of the radiation were higher than expected from the average "superficial dose" and "deep dose" initially documented by the AMP, the volume of actual tissue receiving 3-12 Gy per fraction was requested in order to calculate a more accurate dose-volume effect of the misadministration. These were supplied by the AMP and detailed in a chart below.

	Number of Fractions	Dose per Fraction	Total Dose	Superficial Total Dose	Deep Total Dose	Superficial Equivalent Dose in 2Gy fxs.	Deep Equivalent Dose in 2Gy fxs.	Tissue Affected on CT
Patient 1	3	7	21	9	7.2	10.8	7.8	No CT Avail (presume same as Pt 2): Skin, Muscle
Patient 2	3	7	21	8.1	6.3	9.2	6.4	Skin, Muscle
Patient 3	3	6	18	9.9	5.4	12.5	5.2	Skin, Muscle
Patient 4	5	6	30	22.5	12.5	33.8	13.8	Skin, Muscle

Volume (cc) Receiving X Gy per Fraction

	No. of Fractions	3 Gy	4 Gy	5Gy	6 Gy	7 Gy	8 Gy	9 Gy	10 Gy	11 Gy	12 Gy	Tissue Affected on CT
Patient 2	3	17.4	7.1	2.8	1.2	.5	.2	.04	0	0	0	Skin, Muscle
Patient 3	3	35.7	16.8	7.7	3.1	1.0	.3	.14	.07	.04	.02	Skin, Muscle
Patient 4	5	18.1	6.7	2.2	.5	.07	0	0	0	0	0	Skin, Muscle

Tissue effect Equivalent Dose in 2 Gy Fractions based on number of Fractions, dose per fraction, alpha/beta = 3 (reported in Gy)

	No. of Fractions	3 Gy	4 Gy	5Gy	6 Gy	7 Gy	8 Gy	9 Gy	10 Gy	11 Gy	12 Gy	Tissue Affected on CT
Patient 2	**3**	**10.8**	**16.8**	**24**	**32.4**	**42**	**52.8**	**64.8**	**78**	**92.4**	**108**	**Skin, Muscle**
Patient 3	**3**	**10.8**	**16.8**	**24**	**32.4**	**42**	**52.8**	**64.8**	**78**	**92.4**	**108**	**Skin, Muscle**
Patient 4	**5**	**18**	**28**	**40**	**54**	**70**	**88**	**108**	**130**	**154**	**180**	**Skin, Muscle**

Probable Error Associated with Estimation: < 10% (AMP calculation of dosimetry from CT data)

Method used to Calculate Dose: Provided by Brett Miller, AMP.

Equivalent 2 Gy doses calculated using American Brachytherapy Society HDR conversion to 2 Gy based on Nag, et al IJROBP 46(2):507-513, 2000.

Factual Description of Incident:

Reference: NRC Preliminary Description of Incident Form

The Licensee treated 4 patients with a high dose rate (HDR) after loader using a vaginal cylinder between July and October 2010. On 12/9/2010, one of the licensee's authorized users notified the chief medical physicist that she recognized that two of her patients had skin reddening on their inner thighs. On 12/10/10, the medial physicist measured the transfer guide tube and noted the length was 133.4 cm corresponding to a treatment length of 132cm. Upon review of the patient's medical records, it was noted that the treatment length entered into the treatment planning software was 120cm, resulting in a 12cm difference between the treatment length and the treatment planning length. This resulted in the HDR source traveling 12cm shorter than planned. Review of all vaginal cylinder patients treated since program inception 2/2007, identified two additional patients with the same 12cm error in treatment length. 3 of the 4 patients experienced skin reddening on the inner thighs.

Assessment of probable deterministic effects of the radiation exposure on the individual:

The medical impact of the treatment length error is two-fold: 1) Unintended dosing of skin and muscle in the inner thighs and 2) Underdosing of intended target volume. Each will be addressed separately. Since CT tissue data is not available for patient 1, we will have to assume that patient one will have a similar clinical course as patient 2 who received the same dose/fractionation scheme.

1) Unintended dosing of the skin and muscle in the inner thighs of all 4 patients

Although the Superficial and Deep dose averages were initially provided as an estimated tissue dose by the licensee AMP, these provide a diluted tissue dosing since they average all tissue doses within a 0.5 Gy isodose line; therefore some regions can experience significantly more dose than the average Superficial or Deep reported doses. The AMP provided, upon request, a dose-volume estimation for a range of doses from 3-12 Gy per fraction to more accurately define how much tissue volume received a given dose. Based on American Brachytherapy Society Guidelines (reference cited above), the Equivalent 2 Gy dose was calculated for each patient for each dose and volume. Fortunately, the only tissues receiving significant dose from the provided CT slices were skin and muscle.

Erythema and temporary or permanent hair loss can occur at Equivalent 2 Gy doses of 20-30 Gy. These symptoms would be expected in all patients treated but to smaller tissue volumes in patients 1 and 2 (4.74 cc) than in patient 3 (12.37 cc) or patient 4 (9.47 cc). Skin erythema usually resolves within 3 months after treatment, but can be replaced by hyperpigmentation or mild fibrosis which usually does not impact function, but may impact long-term cosmesis. Therefore patients 3 and 4 may have long term fibrotic changes from the administration that will likely not interfere with function, but may produce long-term cosmetic effects. Given the inner thigh location, these are likely to be hidden by clothes with minimal cosmetic impact to the patient.

The Tolerance Dose at which 5% of patients experience tissue necrosis at 5 years is 70 Gy in Equivalent 2 Gy dosing (Emani, et al IJROBP 21:109-122, 1991). Patients 1 and 2 did not reach this dose exposure. Patient 3 had doses of at least 70 Gy Equivalent to 0.13 cc of tissue, and Patient 4 had doses of at least 70 Gy Equivalent to 0.07 cc. Therefore I would not expect any significant risk of necrosis for patients 1 or 2. Patients 3 and 4 have a small risk of a very small volume of skin necrosis. Given the volumes under 1 cc, it is likely that if these patients experience necrosis, it will be self-resolving with minimal impact to the patient.

Another late effect risk is that of second malignancy with sarcomas as the most common second cancer although this risk in any of the patients is < 1%. As 2 of the patients (patient 1 and 4 are >80 yrs old, this is much less of a risk).

Therefore after detailed analysis of the dosimetry, the significant clinical toxicity impact (both acute and late effects) on each patient from the unintended dosing of the skin and muscle is minimal.

2) Underdosing of intended target volume.

Given the 12cm treatment length discrepancy, the proximal vaginal cuff would have received minimal dose and therefore cancer control of the proximal vaginal cuff would be compromised. This is significant and would need to be addressed with each patient. From the follow-up notes provided and discussion with Dr. Dragovic, this was addressed with each patient.

Briefly Describe the Current Medical Condition of the Exposed Individual:

Follow-up notes detailing the current medical conditions of patients were provided by the AMP.

Patient 1: No obvious ulceration or vaginal vault tumor seen on pelvic exam. Patient with distant metastases.

Patient 2: Mild “radiation changes” with no gross vaginal lesions on pelvic exam. No evidence of cancer recurrence.

Patient 3: Mild transient skin reaction in inner aspect of thighs. No evidence of malignancy on Pap test. Follow-up in 3 months scheduled.

Patient 4: No nodularity on Pelvic exam. No skin changes noted.

Was the Individual or Individual’s Physician Informed of the DOE Long-Term Medical Study Program?

Dr. Dragovic was informed of the DOE LTMSP with contact phone number given during our conversation on 3/22/11. She stated she would give this information to the other treating radiation oncologist Dr. Aref as well.

Based on your review of the incident do you agree with licensee's written report in the following areas:

A. **Why the event occurred: Yes**

B. **Effect on the patient: Yes**

C. **Licensee's immediate actions on discovery: Yes**

D. **Improvements needed to prevent recurrence: Yes, Per the AMP and treating radiation oncologist, new QA procedures have been implemented to decrease the chance of a future recurrence.**

Did the Licensee notify the Referring physician of the misadministration: Yes,

Dr. Dragovic stated in our phone conversation she and Dr. Aref informed all of the referring physicians about all cases within 1 week of the identifying incident.

Did the licensee notify the patient, patient's responsible relative or guardian: Yes

Per our 3/22/11 conversation, Dr. Dragovic stated that she and Dr. Aref informed all patients except for one within one week of the identifying incident. Attempts were made by the licensee to immediately notify the 4th patient, but she changed phone numbers and was difficult to reach. She was eventually notified of the event 1 month ago after several certified letters were sent to her.