Medical Consultant Report

Medical Consultant: Douglas Einstein MD PhD

Report Date: 6-27-2011

Signature: _____

Licensee Name: Crittenton Hospital

Licensee Number: 21-13562-01

Docket Number: 030-02157

Incident Report Date: 3-7-11

Individual Physician/Physicist Names:
Authorized User Radiation Oncologist: V. Elayne Arterbery, MD
Authorized Medical Physicist: Jacek G. Wierzbicki, PHD
Radiation Safety Officer: Judith Bender MD

RECORDS REVIEWED:

1) Initial Description of Incident Dated 3/7/11, 15 day report Dated 2-16-11
2) Preliminary Description of Incident Form from NRC
3) Copies of Dose Volume Histograms (DVHs) and CT Slice Images from AU via Email Dated 5/24/11 and 5/26/11.
4) Dosimetry volume data for dose outside PTV_eval received from AU 6/21/11.

Prescribed and Estimated Dose to Individual or Target Organ:

From Intended and Delivered DVH Data Submitted by Elayne Arterbery, Authorized User Radiation Oncologist

See Dose Analysis PDF

Probable Error Associated with Estimation: < 5% (accuracy of Plato Brachytherapy calculation program and AU definitions of volumes.

Method used to Calculate Dose: Provided by Dr. Elayne Arterbery, MD, Authorized user.

Factual Description of Incident:

Reference: from NRC Preliminary Description of Incident Form, 15 day report dated 2-15-11

Detected during an audit on 2/8/11, for 11 of 12 patients treated with SAVI applicator for accelerated partial breast irradiation (APBI), the treatment was performed using a 2.5mm source step size instead of the planned 5mm step size. This was due to the inability of the licensee to automatically transfer SAVI plans from the planning computer to the treatment computer and the lack of manual change of the default 2.5mm step size to 5mm by the physicist. This resulted in an overdosage of the tissue close to the tip end of the applicator and an underdosage of the tissue closest to the connector end of the applicator.

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

The reference data I used to help analyze the medical impact is documented in the table at the end of this report.

After reviewing the CT reconstructions of each plan for each patient (both intended and delivered), as well as reviewing the dose-volume data provided by the licensee, and discussing the case with the Authorized User, Dr. Arterbery (AMP was not available to discuss case), I feel that the overall the impact on the patient is likely small as was indicated by the licensee. There are, however, several potential effects of the incident on multiple patients that were recognized by the AU and, per my discussions with Dr. Arterbery, were conveyed to the patients and referring physicians.

Issue one: The lumpectomy cavity PTV in every patient was significantly underdosed by 35-52%.

This can result in a lower than expected cancer control and the potential need for another treatment to improve control. Dr. Arterbery stated she addressed this with each patient and the referring physicians.

To date, the licensee stated that they have not seen any breast cancer recurrences in any of the patients involved in the incident.

Issue two: 3 patients had a V150 > 50cc and 7 patients had V200 > 20 cc.

These are the limits set forward in RTOG B-39 trial to decrease the risk of poor cosmesis and fat necrosis. Therefore, these patients who exceeded theses limits are at an increased risk of poor long term cosmesis including skin breakdown and development of fat necrosis which can mimic tumor recurrence on follow-up mammograms and may warrant more frequent biopsies for these patients in the future.

To date the licensee stated that they have not seen any unusual skin reactions in any of the patients.

Issue three: All patients had V150 volume that involved breast tissue outside the intended PTV_eval.

This can result in increased fat necrosis in normal breast tissue outside the intended treatment volume that may mimic out of field recurrences on future mammograms.

To date, the licensee stated that they have not seen any breast cancer recurrences in any of the patients involved in the incident.

Issue four: Five patients had V150 volume involving the ribs.

This has the potential for increased risk of rib fracture for these 5 patients.

To date the licensee has not detected any rib fractures in any of the patients.

Briefly Describe the Current Medical Condition of the Exposed Individual:

Per my phone conversations with Dr. Arterbery and the licensee reports, no patient have experienced any toxicity or recurrences from the incident treatment.

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

Dr. Arterbery (Physician for all patients) was informed during our phone conversations of the DOE LTMSP.

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

- Although not completely described on the report, per my conversations with Dr. Arterbery, all patients were informed of potential increased risk of fat necrosis, skin toxicity, sub-optimal cosmesis, rib fracture, and sub-optimal potential cancer control.

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

D. **Improvements needed to prevent recurrence:** Yes

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

Per the 15 day report, the authorized user notified referring physicians of the events 2/9/11 (1 day after detection).

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

Per our phone conversations, patients were notified 2/8/11 and 2/9/11 by the authorized user.

Reference Data for Side effects of APBI HDR Brachytherapy (SAVI device is hybrid balloon brachytherapy and interstitial brachytherapy)

Wazer DE. et al. IJROBP 64:489-95, 2006 -- Long Term Interstitial HDR APBI data (Median FU 73 months) since no long term SAVI data exists

Brashears JE, et al. Brachytherapy 8:19-25, 2009 – late chest wall toxicity after balloon brachytherapy

NSABP B-39 Guidelines

PATIENT 1

Parameter	PTV-EVAL \ Intended Volume inside PTV-eval	Delivered volume inside PTV-EVAL	Underdosed volume inside PTV-EVAL	% underdose	Excess Dose in PTV-Eval	Delivered volume outside PTV-EVAL	Total Volume of high dose regions	Excess from intended in high dose regions	Location of unintended volume outside PTV-EVAL
v90	61.43	55.67	33.21	-22.46	40%	36.15			Breast (majority), skin, rib and lung
V150		20.56	25.05		4.49	6.04	31.09	10.53	Breast
V200		10.22	17.06		6.84	2.88	19.94	9.72	Breast

PATIENT 2

Parameter	PTV-EVAL \ Intended Volume inside PTV-eval	Delivered volume inside PTV-EVAL	Underdosed volume inside PTV-EVAL	% underdose	Excess Dose in PTV-Eval	Delivered volume outside PTV-EVAL	Total Volume of high dose regions	Excess from intended in high dose regions	Location of unintended volume outside PTV-EVAL
v90	125.63	113.65	65.08	-48.57	43%	52.92			Breast (majority), skin, rib and lung
V150		34.89	42.99		8.10	4.02	47.01	12.12	Breast and rib
V200		15.12	26.28		11.16	0	26.28	11.16	Breast and rib

PATIENT 3

Parameter	PTV-EVAL \ Intended Volume inside PTV-eval	Delivered volume inside PTV-EVAL	Underdosed volume inside PTV-EVAL	% underdose	Excess Dose in PTV-Eval	Delivered volume outside PTV-EVAL	Total Volume of high dose regions	Excess from intended in high dose regions	Location of unintended volume outside PTV-EVAL
v90	44.9	40.75	24.33	-16.42	40%	21.97			Breast (majority), skin, rib and lung
V150		18.13	16.75		-1.38	3.87	20.62	2.49	Breast, rib and skin
V200		9.27	11.64		2.37	0.73	12.37	3.10	Breast and skin

PATIENT 4

Parameter	PTV-EVAL \ Intended Volume inside PTV-eval	Delivered volume inside PTV-EVAL	Underdosed volume inside PTV-EVAL	% underdose	Excess Dose in PTV-Eval	Delivered volume outside PTV-EVAL	Total Volume of high dose regions	Excess from intended in high dose regions	Location of unintended volume outside PTV-EVAL
v90	107.16	97.39	56.30	-41.09	42%	34.51			Breast (majority), skin, and rib
V150		34.55	34.91		0.36	2.05	36.96	2.41	Breast
V200		17.78	20.98		3.20	1.34	22.32	4.54	Breast

PATIENT 5

Parameter	PTV-EVAL \ Intended Volume inside PTV-eval	Delivered volume inside PTV-EVAL	Underdosed volume inside PTV-EVAL	% underdose	Excess Dose in PTV-Eval	Delivered volume outside PTV-EVAL	Total Volume of high dose regions	Excess from intended in high dose regions	Location of unintended volume outside PTV-EVAL
v90	86.26	84.74	40.55	-44.19	52%	44.31			Breast (majority), rib, and lung
V150		37.05	32.59		-4.46	7.26	39.85	2.80	Breast and rib
V200		17.90	23.24		5.34	2.41	25.65	7.75	Breast

PATIENT 6

Parameter	PTV-EVAL \ Intended Volume inside PTV-eval	Delivered volume inside PTV-EVAL	Underdosed volume inside PTV-EVAL	% underdose	Excess Dose in PTV-Eval	Delivered volume outside PTV-EVAL	Total Volume of high dose regions	Excess from intended in high dose regions	Location of unintended volume outside PTV-EVAL
v90	50.60	50.00	32.68	-17.32	35%	27.41			Breast (majority), skin, rib and lung
V150		22.53	24.49		1.96	1.07	25.56	3.03	Breast, Rib, and Skin
V200		11.79	15.55		3.76	0.50	16.05	4.26	Breast and rib

PATIENT 7

Parameter	PTV-EVAL \ Intended Volume inside PTV-eval	Delivered volume inside PTV-EVAL	Underdosed volume inside PTV-EVAL	% underdose	Excess Dose in PTV-Eval	Delivered volume outside PTV-EVAL	Total Volume of high dose regions	Excess from intended in high dose regions	Location of unintended volume outside PTV-EVAL
v90	129.21	120.79	68.54	-52.25	43%	61.42			Breast
V150		45.41	44.10		-1.31	10.65	54.75	9.34	Breast
V200		17.02	28.22		11.20	7.20	35.42	18.40	Breast

PATIENT 8

Parameter	PTV-EVAL \ Intended Volume inside PTV-eval	Delivered volume inside PTV-EVAL	Underdosed volume inside PTV-EVAL	% underdose	Excess Dose in PTV-Eval	Delivered volume outside PTV-EVAL	Total Volume of high dose regions	Excess from intended in high dose regions	Location of unintended volume outside PTV-EVAL
v90	93.51	93.36	51.23	-42.13	45%	53.52			Breast
V150		41.78	35.68		-6.10	9.75	45.43	3.65	Breast
V200		18.54	26.68		8.14	1.48	28.16	9.62	Breast

PATIENT 9

Parameter	PTV-EVAL \ Intended Volume inside PTV-eval	Delivered volume inside PTV-EVAL	Underdosed volume inside PTV-EVAL	% underdose	Excess Dose in PTV-Eval	Delivered volume outside PTV-EVAL	Total Volume of high dose regions	Excess from intended in high dose regions	Location of unintended volume outside PTV-EVAL
v90	127.79	123.43	64.70	-58.73	48%	66.15			Breast and rib
V150		46.18	44.99		-1.19	7.06	52.05	5.87	Breast
V200		17.15	32.91		15.76	0.00	32.91	15.76	Breast

PATIENT 10

Parameter	PTV-EVAL \ Intended Volume inside PTV-eval	Delivered volume inside PTV-EVAL	Underdosed volume inside PTV-EVAL	% underdose	Excess Dose in PTV-Eval	Delivered volume outside PTV-EVAL	Total Volume of high dose regions	Excess from intended in high dose regions	Location of unintended volume outside PTV-EVAL
v90	114.74	113.74	60.50	-53.24	47%	68.31			Breast, rib, and lung
V150		45.41	42.61		-2.80	11.43	54.04	8.63	Breast
V200		23.25	30.73		7.48	2.46	33.19	9.94	Breast

PATIENT 11

Parameter	PTV-EVAL \ Intended Volume inside PTV-eval	Delivered volume inside PTV-EVAL	Underdosed volume inside PTV-EVAL	% underdose	Excess Dose in PTV-Eval	Delivered volume outside PTV-EVAL	Total Volume of high dose regions	Excess from intended in high dose regions	Location of unintended volume outside PTV-EVAL
v90	67.01	61.58	36.99	-24.59	40%	29.40			Breast, rib, and lung
V150		26.20	26.36		0.16	2.35	28.71	2.51	Breast and rib
V200		14.74	18.05		3.31	0.00	18.05	3.31	Breast

		Effect of event
% of PTV_Eval Underdosed:	35-52%	Lower than expected cancer control, need for another procedure to improve cancer control
V150 > 50 cc	3 patients	Increased risk of poor cosmeis and fat necrosis
V200 > 20 cc	7 patients	Increased risk of poor cosmeis and fat necrosis
V150 involving skin	2 patients	Late skin toxicity and poor cosmetic outcome
Breast tissue with unintended V150, V:	All patients	Increased risk of fat necrosis outside lumpectomy that may be difficult to discern from recurrence
V150 involving rib	5 patients	Increased risk of late rib fracture