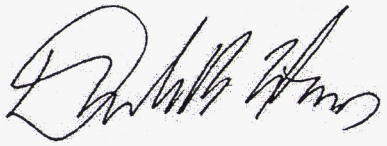
**Medical Consultant Report**

**Medical Consultant:** Douglas Einstein MD PhD

**Report Date:** 1/16/11



**Signature:** _____

**Licensee Name:** Community Hospitals of Indiana

**Licensee Number:** 13-06009-01

**Docket Number:** 030-01625

**Incident Date:** 10/6/10

Individual Physician/Physicist Names:
Authorized User Radiation Oncologist: Jianan Graybill, MD
Authorized Medical Physicist: Bill Howard
Radiation Safety Officer: Andrea Browne, PhD

**RECORDS REVIEWED:**

1) Initial Description of Incident Dated 10/8/10
2) Preliminary Description of Incident Form from NRC
3) Copies of Dose Volume Histograms (DVHs) and CT Slice Images from Bill Howard, AMP via Email Dated 12/27/10
4) Review of CT dosimetry via VPN to treatment machine 12/29/10 together with Bill Howard over the phone and computer.
5) Emailed PDF's of DVH's and CT image Slices from Bill Howard 12/30/10 and 1/3/11

**DOSING:**

**Prescribed and Estimated Dose to Individual or Target Organ:**

From Intended and Delivered DVH Data Prepared from Oncentra Masterplan Software by Bill Howard, AMP of Licensee

| | Dose (%) | Dose (cGy) | Intended Volume (%) | Delivered Volume (%) | Intended Volume (ccm) | Delivered Volume (ccm) | Difference From Intended (ccm) | Interpretation |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| Entire Breast/Chest wall (Intended PTV-Eval + extra tissue on CT slices) | 200 | 6800 | 3.77 | 3.84 | 45.68 | 47.61 | 1.93 | Increased dose to 1.93cc of Unintended Breast Tissue |
| | | | | | | | | |
| Within intended PTV-Eval | 100 | 3400 | 94.40 | 87.54 | 81.45 | 75.51 | -5.94 | Under-dosing of 5.94cc of Intended Breast Tissue |
| Within intended PTV-Eval | 150 | 5100 | 41.92 | 42.29 | 36.17 | 36.48 | 0.31 | Not significant difference |
| Within intended PTV-Eval | 200 | 6800 | 19.15 | 19.01 | 16.53 | 16.40 | -0.13 | Not significant difference |
| | | | | | | | | |
| Rib | 73.34 | 2493.5 | 0.36 | 0.36 | 0.1 | 0.10 | 0.00 | Not significant difference |
| Skin | 145 | 4930 | 0.00 | 0.16 | 0 | 0.12 | 0.12 | Increased Dose to very small volume of unintended skin |

**Probable Error Associated with Estimation:** < 5% (accuracy of Oncentra Master Plan Version 3.3 SP3 Brachytherapy calculation program and AMP definitions of volumes.

**Method used to Calculate Dose**: Provided by Bill Howard AMP via CT Image Slices and Dose Volume Histograms he calculated.

**Factual Description of Incident:**

Reference: from NRC Preliminary Description of Incident Form, Community Health Network Medical Event Report. ,

Following the 8th Fraction of a planned 10 fraction SAVI applicator HDR brachytherapy treatment for left breast cancer, the AMP discovered an error in the treatment plan. The AMP remembered that he did not switch the "start at" position, which tells the computer where to start the applicator reconstruction and the HDR device where to start source placement, to "tip end" from the program default of "connector end". This caused the source placement to be flipped 180 degrees along the applicator's long access. Therefore, the tip end of the applicator did not receive its intended dose, and areas closer to the connector end of the applicator received a higher-than-intended dose. The authorized user then modified the written directive to add two fractions beyond the 10 prescribed fractions to make up the underdosing of the intended region near the applicator tip.

**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. The NRC inspector highlighted point doses in his initial report, although in HDR brachytherapy there are always high point doses near the sources in every HDR brachytherapy planned administration and the medical impact to the patient is predominantly determined by dose-volume limits rather than point dose limits. Therefore dose-volume limits were utilized to assist with my determination of medical effects on the patient.

After reviewing the plan on the treatment computer via VPN, discussing the case with the AMP and Dr. Graybill (the authorized user), and analyzing the DVH's and images provided by the licensee, I agree that overall the impact on the patient is likely small as was indicated by the licensee. There are, however, two issues that were recognized by the licensee. Per my conversation with the AU Dr. Graybill these issues were conveyed to the patient and the referring physician.

**Issue one:** There is an excess of V200 dose to 1.93 cm of breast tissue, chest wall, and skin that was not intended. The implications of this are a potential for increased fat necrosis that can mimic tumor recurrence on follow-up mammograms and may warrant more frequent biopsies for the patient in the future, potential for late skin breakdown, and potential for less than excellent cosmesis. This is based on interstitial breast brachytherapy data summarized below with

references sited. The excess V200 volume was small enough that it did not definitively raise the risk of a worse outcome grade in any category and therefore the impact on the patient will likely be small.

Issue two: there is an underdosing of 5.93cm of intended breast tissue. This can potentially decrease tumor control in this region, but volume is a small percentage (7%) of lumpectomy cavity PTV-eval (81.45cm) and patient is receiving chemotherapy per Dr. Graybill, therefore this risk is likely small.

**Briefly Describe the Current Medical Condition of the Exposed Individual:**

Per my phone conversation with Dr. Graybill on 1/10/11, there are chart notes from 12/7/10 (last contact) where patient's husband was contacted over the phone who stated that patient had started chemotherapy, had no complaints, and specifically has had no health problems or breast problems.

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

Dr Graybill (Patient's physician) was informed during our conversation on 1/10/11 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

- Per my conversation with Dr. Graybill on 1/10/11, the patient was informed of potential increased risk of fat necrosis, skin toxicity, sub-optimal cosmesis, and small area of underdosed lumpectomy cavity.

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,

Dr. Graybill stated in our phone conversation 1/10/11 that she informed the referring physician in a letter dated 10/7 that was transcribed 10/8.

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

Per our 1/10/11 conversation, Dr. Graybill states she informed the patient within 1 day of the incident on 10/7/10 after the incident.

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

References

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

| **Side Effect: Fat necrosis** | | | | | | | | | **Interpretation** |
|---|---|---|---|---|---|---|---|---|---|
| | | | Published Data | | | | 10-6-10 Event | | |
| Significant Variable | | No Fat Necrosis | | Fat necrosis | | Intended | | Delivered | |
| V150 (ccm) | | 44 | | 69 | | 36.48 | | 36.17 | |
| V200 (ccm) | | 13 | | 22 | | 16.40 | | **18.46** | **Above low grade cutoff level** |
| | | | | | | | | (16.53ccm in PTV eval + 1.93ccm outside PTVeval | |
| **Side Effect: Late Subcutaneous Toxicity** | | | | | | | | | |
| | | | Published Data | | | | 10-6-10 Event | | |
| Significant Variable | | Grade 0/1 | | Grade > 2 | | Intended | | Delivered | |
| DHI | | | | | | | | | |
| ((V100-V150/V150) | | 0.77 | | 0.73 | | 0.56 | | 0.52 | **Outside limit, but similar to intended** |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Side Effect: Late Skin Toxicity** | | | | | | | | | |
| | | | Published Data | | | | 10-6-10 Event | | |
| Significant Variable | | Grade 0 | | Grade 1/2 | | Intended | | Delivered | |
| DHI | | 0.77 | | 0.71 | | 0.56 | | 0.52 | |
| V150 (ccm) | | 44 | | 62 | | 36.48 | | 36.17 | |
| V200 (ccm) | | 13 | | 20 | | 16.40 | | **18.46** | **Above low grade cutoff level** |
| | | | | | | | | | |
| **Side Effect: Long Term Cosmetic Outcome** | | | | | | | | | |
| | | | Published Data | | | | 10-6-10 Event | | |
| Significant Variable | | Excellent | | Good/Fair/Poor | | Intended | | Delivered | |
| DHI | | 0.77 | | 0.73 | | 0.56 | | 0.52 | |
| V150 (ccm) | | 43 | | 59 | | 36.48 | | 36.17 | |
| V200 (ccm) | | 13 | | 19 | | 16.40 | | **18.46** | **Above low grade cutoff level** |
| **Side Effect: Rib Injury** | | | | | | | | | |
| | | | Published Data | | | | 10-6-10 Event | | |
| Significant Variable | | | Late Rib Fracture | | | | Delivered | | |
| V37 | | | 37Gy to 15.9% | | | | 29 Gy to < 1% | | |
| V44 | | | 44 Gy to 6.6% | | | | 29 Gy to < 1% | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Side Effect: Skin Toxicity (NSABP B-39)** | | | | | | | | | |
| | | | Published Data | | | | 10-6-10 Event | | |
| Significant Variable | | | Upper limit | | | | Delivered | | |
| V145 | | | 0% | | | | <1% | | **Above low grade cutoff level** |