

October 8, 2010

U.S. NRC Region III
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352
Attn: Darrel Wiedeman

Dear Mr. Wiedeman:

Per our conversation this morning concerning a possible medical event at Community Hospital East, we have notified the NRC Operations Center by telephone at 9:57 EDT.

This written report is to comply with 10 CFR 35.3045 (3)(d)(1).

Licensee's Name: Community Hospitals of Indiana, Inc.

Prescribing Physician: Jianan Graybill, M.D.

Description of Event: It was discovered after treating 8 fractions of a SAVI partial breast HDR brachytherapy that an error was made in the reconstruction of the catheters. This resulted in a small area receiving too much dose and a small area receiving too little dose. The physician was informed and fractions 9 and 10 were adjusted to compensate. Two additional fractions were given to compensate for the under dosed area. The result of all 12 fractions was determined to be within the criteria prescribed by the physician. The authorized user's written directive states that no more than 20cc of tissue should receive more than 200% of the prescribed dose, and only 19cc of tissue received more than 200%.

Reason event occurred: Treatment planning system default entry of catheter position not changed.

Effect on individual: Radiation Oncologist expects no adverse result to patient.

Action taken to prevent recurrence: Written procedure modified to add a check step in the planning process to verify that the catheters are reconstructed correctly.

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Header Line 1
Header Line 2

Individual notification: The patient was notified of the error by the radiation oncologist and scheduled for the two additional treatments to correct the under dose.

As supporting documentation that even with the treatment planning error, the radiation dose was delivered in accordance with the written directive, a blank copy of the written directive form has been included with this letter. If you need more information, please contact me at (317) 355-5865 or Bill Howard at (317) 355-5347.

Sincerely,

A handwritten signature in cursive script that reads "Andrea D. Browne".

Andrea D. Browne, Ph.D.
Radiation Safety Officer

Place Patient
Sticker Here

SAVI
Accelerated Partial
Breast Irradiation
HDR Brachytherapy Prescription

| Written Directive | | | | | |
|-----------------------------|--|---------------------------------------|---------|---------------------|----|
| Treatment Site | <input type="checkbox"/> Left Breast | <input type="checkbox"/> Right Breast | Isotope | Ir-192 | |
| Total HDR Dose (cGy) | 3400 | Dose per Fraction (cGy) | 340 | Number of Fractions | 10 |
| Prescription Point | 1 cm from cavity | | | | |
| Fractionation | Treat twice per day with 6 hrs minimum between fractions | | | | |
| Comments: | ≤400 cGy/fx to dermal layer of skin ≤375 cGy/fx to ribs | | | | |
| Signature (authorized user) | | Date | | | |

| Applicator | | | |
|-----------------------------|-----------------------------------|------------------------------------|----------------------------|
| | <u>Device</u> | | <u>Length x width (cm)</u> |
| | <input type="checkbox"/> 6-1 Mini | | 5.0 x 2.4 |
| | <input type="checkbox"/> 6-1 | | 6.1 x 3.0 |
| | <input type="checkbox"/> 8-1 | | 6.7 x 4.0 |
| | <input type="checkbox"/> 10-1 | | 7.5 x 5.0 |
| Catheter 1 Reference Length | mm | Catheter 8 Reference Length | mm |
| Catheter 2 Reference Length | mm | Catheter 9 Reference Length | mm |
| Catheter 3 Reference Length | mm | Catheter 10 Reference Length | mm |
| Catheter 4 Reference Length | mm | Catheter 11 Reference Length | mm |
| Catheter 5 Reference Length | mm | | |
| Catheter 6 Reference Length | mm | Distance from handle to skin | mm |
| Catheter 7 Reference Length | mm | Skin mark lines up with Catheter # | |

| Treatment Criteria and Planning Information | | |
|---|--------------------------|-----------|
| | Criteria | Plan Data |
| Cavity to skin surface distance | | mm |
| Maximum dose to dermal layer of skin | ≤400 cGy/fx | cGy/fx |
| Maximum rib dose | ≤375 cGy/fx | cGy/fx |
| Percent of PTV that is air or seroma | <10% | % |
| V150 | vol to receive 150% Dose | cc |
| V200 | vol to receive 200% Dose | cc |