

**HOSPITAL ANDRÉS GRILLASCA, INC.**

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSIA, PENNSYLVANIA 19406-1415

December 6, 2005

SUBJECT: Identified Medical Event for License No. 52-11832-02.

On November 29, 2005 a possible Medical Event was identified by the Authorized Medical Physicist of our license, this event was explained and notified to the NRC Operation Center (301-951-0550), the same day and an NRC Inspector (Hector Bermudez) visited our facility on November 30, 2005.

The present letter is the written notification as per 10 CFR 35.3045:

- (i) Hospital Andres Grillasca
- (ii) Jose Correa, MD
- (iii) The dwell time was calculated to deliver a dose to points at a distance of 10mm and the prescription was at a distance of 20mm so that the dose received at 20mm was (an average of) 259cGy instead of the prescribed 600cGy. This mistake occurred in the third fraction and was detected before the fourth fraction was administered. The first, second and fourth fractions were delivered correctly. The total number of fractions is five.
- (iv) There was a miscommunication between the doctor and the dosimetrist. The dosimetrist understood that the dose was to be delivered to a 10mm distance. The physicist did not check the previous treatment time to verify time differences between previous and current plan (during this verification, before the fourth fraction, the current event was detected).
- (v) There is no adverse effect on the patient from this event.
- (vi) To prevent event, a verification of the time of previous treatment will be conducted by the physicist before each fraction on all patients, also distance of prescription will be double check verbally (with doctor) and on the prescription.
- (vii) The patient was notified by Jose Correa, MD on November 30, 2005.

Manuel J. Vázquez
Administrator
Hospital Andres Grillasca
P.O. Box 331324
Ponce, PR 00733-1324

NMSS/RGNI MATERIALS-004

HOSPITAL ANDRES GRILLASCA
HDR-AFTERLOADING BRACHYTHERAPY PRESCRIPTION AND DELIVERY

Patient Name: [REDACTED] Rec#: [REDACTED] Radiation Oncologist: J.C. C.R.
 Patient ID(2 required): Hospital ID SSN Driver's License Photo ID Voter ID
 Diagnosis: Cervix T ___ N ___ M ___ Stage: I II III IV
 Implant Site: Vagina Uterus Esophagus Bronchial Others _____
 FX#: 5

PRESCRIPTION AND DELIVERY (to be completed by the attending physician)

Dose Prescription Points: @ Point A @ the surface of the cylinder(2 cm) Other (20 mm) 2 cm dist. from

Date	Fx No.	Prescription Dose (cGy)	Applicator Type	Applicator Size (nominal)	HDR Loading(Tandem and ovoid) or No. of Active Positions(Vaginal Cylinder)	MD Initial	Delivered Dose (cGy)	MD Initial after delivery
11/8/05	1	600	Tandem + Vag Spacers	Tandem + 2.5cm spacers	17 dwell positions	J.C.	600	J.C.
11/15/05	2	600	Tandem + spacers	Tandem + Vaginal spacers 2.5cm	19 dwell positions	J.C.	600	J.C.
11/22/05	3	300	Tandem + spacers	uterine tandem + 2.5cm spacers	19 dwell positions	J.C.	300	J.C.
11/29/05	4	600	Tandem + spacers	uterine tandem + 2.5cm spacers	19 dwell positions	J.C.	600	J.C.
12/6/05	5	400 700	Tandem + spacers	uterine tandem + 2.5cm spacers	17 dwell positions	J.C.	700	J.C.

Total Dose Delivered (cGy) 2800 Modification (if any) The Dose of Fx # 3 was calculated at 1 cm (10mm) distance from sources instead of the prescribed 2cm distance. J.C.

Survey before discharge the patient: Survey meter 1. Ludlum Model 2241 S/N 160865 2. Ludlum Model 14C S/N 14861

Date <u>11/8/05</u>	S. Meter <u>1</u>	Bkg Reading <u>10</u> μ R/hr	Discharge Reading <u>12</u> μ R/hr	Done by <u>[Signature]</u>
Date <u>11/15/05</u>	S. Meter <u>1</u>	Bkg Reading <u>8</u> μ R/hr	Discharge Reading <u>10</u> μ R/hr	Done by <u>[Signature]</u>
Date <u>11/22/05</u>	S. Meter <u>1</u>	Bkg Reading <u>10</u> μ R/hr	Discharge Reading <u>13</u> μ R/hr	Done by <u>[Signature]</u>
Date <u>11/29/05</u>	S. Meter <u>1</u>	Bkg Reading <u>7</u> μ R/hr	Discharge Reading <u>9</u> μ R/hr	Done by <u>[Signature]</u>
Date <u>12/6/05</u>	S. Meter <u>1</u>	Bkg Reading <u>5</u> μ R/hr	Discharge Reading <u>9</u> μ R/hr	Done by <u>[Signature]</u>

Patient points

Point	X (mm)	Y (mm)	Z (mm)	Norm dose	Dose (%)	Dose (cGy)
BLADD.	-16.5	-36.0	-21.9	100.00	18.08	108.47
RECTO	0.2	28.9	-5.8	100.00	27.69	166.14

Shift (mm)
2.8
1.4

Applicator points

No points.

Reference points

No points.

Dose points

Dose points on axis:

Point	X (mm)	Y (mm)	Z (mm)	Norm dose	Dose (%)	Dose (cGy)
1	10.6	-15.5	41.2	100.00	68.14	408.84
2	10.4	-13.3	36.6	100.00	85.26	511.58
3	10.3	-11.2	32.1	100.00	95.75	574.49
4	10.1	-9.1	27.6	100.00	101.83	610.99
5	9.9	-7.0	23.0	100.00	105.58	633.45
6	9.8	-4.9	18.5	100.00	107.54	645.22
7	9.4	-3.4	13.8	100.00	112.05	672.29
8	9.5	-2.2	8.9	100.00	111.02	666.09
9	9.7	-1.1	4.1	100.00	109.77	658.60
10	9.7	-0.5	-0.9	100.00	110.42	662.54
11	9.8	0.1	-5.9	100.00	110.06	660.33
12	9.8	0.6	-10.8	100.00	108.85	653.09
13	9.6	0.6	-15.8	100.00	109.63	657.76
14	9.6	0.5	-20.8	100.00	108.04	648.22
15	9.6	0.4	-25.8	100.00	105.46	632.78
16	9.7	0.3	-30.8	100.00	101.75	610.52
17	9.7	0.2	-35.8	100.00	95.77	574.65
18	9.7	0.1	-40.8	100.00	85.59	513.53
19	9.8	0.0	-45.8	100.00	68.86	413.13
20	-9.4	-15.5	41.2	100.00	70.53	423.17
21	-9.6	-13.3	36.6	100.00	86.72	520.29

Step size: 5.0 mm

Ref	Channel 1	
	1500 mm	
Pos	Plan(s)	Act(s)
1	14.3	14.3
2	14.3	14.3
3	14.3	14.3
4	14.3	14.3
5	14.3	14.3
6	14.3	14.3
7	14.3	14.3
8	14.3	14.3
9	14.3	14.3
10	14.3	14.3
11	14.3	14.3
12	14.3	14.3
13	14.3	14.3
14	14.3	14.3
15	14.3	14.3
16	14.3	14.3
17	14.3	14.3
18	14.3	14.3
19	14.3	14.3
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Prescribed @ 2cur
 Calculated @ 1cur
 delivered @ 1cur

Called NRC, For Medical Event Report

1/29/05 @ 3:40 pm (NRC Time)
 4:40 pm (our time)

321-951-0550

Discoloration 11/29/05

Dose Received by Points

143.26	288.23
212.94	286.76
237.32	280.46
296.30	270.18
270.55	255.92
281.61	286.96
292.45	212.57
293.42	182.53
292.33 292.33	
293.42	
292.03	