



Status of Medical Events FY 2011

Donna-Beth Howe, Ph.D.
Medical Radiation Safety Team
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Medical Events 2011

- **49 Medical events reported - FY 2010**
- **58 Medical events reported - FY 2011**

	<u>FY10</u>	<u>FY11</u>
35.200	1	3
35.300	4	6
35.400	25	26 (2?)
35.600	12	12
35.1000	7	11

Medical Events 2011

Diagnostic Medical Event

35.200 3

I-123 contaminated with I-131 1

- Oral I-123 capsule given
- Excessive image background observed
- Both I-123 and I-131 peaks seen
- Vial cap contaminated with I-131
- 380 cGy (rad) to thyroid of child

Medical Events 2011

35.200 (continued)

I-123 intended I-131 given 1

- 5 mCi I-131 given instead of prescribed 5 mCi I-123

In-111 (Octreotide) intended Sr-89 1

- Picked up expired Sr-89 syringe
- 63 cGy (rem) dose to bone marrow

Medical Events 2011

35.300 Medical events

6

- Phosphorus 32 (2 patients) 1
 - Treating Cystic Craniopharyngioma
 - Notices inflammation surrounding cyst and drainage catheter
 - Expected doses of 30,000 and 20,000 rads received 56,500 and 50,700 rads
 - Drug manufacturer measurement issue

Medical Events 2011

35.300 (continued)

– Samarium-153

1

- Syringe connected to 3 way stopcock
- Removed syringe at wrong time
- Lost some activity before reconnecting syringe
- Prescribed 25.6 mCi delivered 14.8 mCi

Medical Events 2011

35.300 (continued)

- Oral Sodium Iodide I-131 4
 - Prescribed 25 mCi assayed 19.9 mCi; physician accepted the higher dosage; written directive was not changed
 - Prescribed 20 mCi gave 100 mCi intended for another patient
 - Prescribed 150 mCi received 75 mCi – one capsule left in vial
 - Prescribed 2 mCi gave 1.58 mCi found on audit

Medical Events 2011

35.400 Medical events

26 (2?)

– Biliary Duct	1
– Prostate	25
– Prostate undetermined	2

35.400 Medical Events

Biliary Duct Ir-192 1

- Intended dose of 20,000cGy (rad) delivered 124 cGy (rad)
- Guide wire moved 5 cm during administration

35.400 Medical Events

Prostate (81 Patients) 25

8 licensees had multiple medical events -

- Our Lady of Bellefonte Hospital - 35
- Highlands Regional Medical Center – 3
- Western Baptist Hospital - 3
- Saint Nicholas Hospital – 6
- Saint Vincent Hospital - 9
- Saint Mary's Hospital – 2
- Gundersen Lutheran Medical Center - 3
- Saint Elizabeth Hospital - 3

35.400 Medical Events

Prostate (continued)

8 licensees had multiple medical events –

- Poor records, no written directives, no post-implant CT, no post implant doses recorded
- Not reviewing cases against medical event criteria
- Poor image quality post-operative CT
- Clinical limitations of the techniques working on improving processes
- No reason given

35.400 Medical Events

Prostate (Other 17 licensees)

- 8 Suboptimal dose distribution, poor placement, poor/no visualization, incorrect identification of prostate
- 3 Tumor volume increase due to edema
- 2 under dose to the prostate, no definitive reason
- 1 Air kerma - over dose
- 1 Prescribed partial treatment gave full
- 1 Two sets of seed for one patient
- 1 Anatomy issues



35.400 Medical Events

Prostate Undetermined

2 licensees with overdoses (8 patients) –

- NRC is reviewing

Medical Events 2010

35.600 Medical events **12**

– HDR **10**

- Savi 8 (15 patients) **4**
- Breast Balloon **1**
- Broncial **2**
- Other **3**

– Gammaknife **2**

35.600 Medical Events

HDR Savi-8 (15 patients) 4

- Did not reset default dwell positions - 5mm steps prescribed gave 2.5 mm (11 patients)
- Did not reset start position default from connector end
- Wrong catheter length – wire marker stopped at maximum curvature not end (2 patients)
- source punched through catheter 500-5,00 cGy (rad) to the skin

35.600 Medical Events

HDR (continued)

Breast Balloon

1

- Ultrasound was used to image the balloon before one fraction – inoperable CT scanner
- Drainage was observed at the surgical incision
- Balloon discovered to be drained at next visit
- Possibly 680 cGy (rad) double dose

35.600 Medical Events

HDR Bronchial

2

- Wrong site – orientation error – 1,500 to 2,000 cGy (rad) to larynx region.
- Wrong site - Dwell positions in treatment plan misrepresented – larynx received 233 cGy (rad) intended 42 cGy (rad)

35.600 Medical Events

HDR Other (6 patients) 3

- 60% under dose - physicist did not calculate effect of tube used to deliver
- Wrong transfer tube – length was 12 cm longer than treatment length – skin reddening 270 to 450cGy (rad) (4 patients)
- Wrong transfer tubes on 3 of 4 catheters for 3 fractions - overdose to skin – 59% under dose to treatment site

35.600 Medical Events

Gammaknife

2

- Computer screen froze due to computer programming problem - patient removed
- Prescribed 1,600 cGy (rad) delivered 85 cGy (rad) – physicist forgot to adjust weight factor

Medical Events 2011

35.1000 Medical events	11
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– TheraSphere Microspheres	8
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– SirSphere Microspheres	3
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35.1000 Medical Events

Theraspheres

8

- Shunting to duodenum 9,000 cGy (rad)
- Wrong site – intended right lobe treated left
- Transcription error in order did not compare activity to written directive intended 11,600 cGy (rad) received 25,700cGy (rad)

35.1000 Medical Events

TheraSpheres (continued)

- Physicist used wrong segment volume – prescribed 7,440 cGy (rad) received 15,940 cGy (rad)
- Plunger accidentally rotated – pause resulted in microspheres settling in catheter prescribed 9,400 cGy (rad) received 7,000 cGy (rad)
- Microsphere clump visualized – could not flush prescribed 9,750 cGy (rad) received 3,760 cGy (rad)

35.1000 Medical Events

TheraSpheres (continued)

- Saline leak in administration line – received 64% of intended dose
- Failure of septum of vial – prescribed 8,000 cGy (rad) received 4,900 cGy (rad)

35.1000 Medical Events

SirSpheres

3

- Treatment terminated patient pain – 50 % of prescribed dose
- Occlusion of the micro-catheter – sphere concentration too high - prescribed 6,300 cGy (rad) received 1,480 cGy (rad)
- Medical physicist read written directive incorrectly

Acronyms

- FY – Fiscal Year
- HDR – High Dose Rate Remote Afterloader
- Sr - Strontium



QUESTIONS?