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Fiscal Year 2010-2011 Medical Events Presentation

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Diagnostic Medical Events

- 35.200 (n=4)
- I-123 contaminated with I-131
  - 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

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§35.200 (continued)

- I-131 "technical ME": low dose by ≥ 20%: 20 uCi)
- I-123 intended but I-131 given
  - 5 mCi I-131 given instead of 5 mCi I-123
- In-111 (Octreotide) intended but Sr-89 given(!)
  - Picked up expired Sr-89 syringe
  - 63 cGy (rem) dose to bone marrow

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§35.300 Radiopharmaceutical Written Directive

Total of 9* Medical Events (ME)

- I-131 Tx - 4
- Sm-153 - 2
- I-131* I-123 prescribed
- Sr-89* In-111 Octreotide prescribed

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§35.400 Manual Brachytherapy

- Last manual afterloader ME's were on 3/5/2010 and 07/06/2010 and Reported to NRC 08/11/2010 and 08/03/2010 respectively
- Zero Sr-90 eye applicator brachytherapy ME's
- Last vascular brachytherapy ME was in 06/09/2010 (but probably very few being performed)

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Permanent implant prostate brachytherapy

- 30 ME's involving 94 patients
- 17 ME's (81 pts) that were reported during this period actually occurred more than 6 months prior to being reported with some as far back as 2003

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Permanent implant prostate brachytherapy

- Isotope data not available on all but at least:
  - Pd-103 $\geq$ 18 pts
  - I-125 $\geq$ 34 pts
  - Cs-131 $\geq$ 1 pts

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Causes

- The most frequent cause of Medical Events identified during the reporting timeframe was underdosing (e.g. D90 <80%): n ≥ 39
- Overdose (based on D90): n ≥ 18
- One I-125 normal tissue overdose (bladder, small and large bowel) due to incorrect seed placement

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Causes

- One ME using Pd-103 was due to use of WRONG SEEDS
  - 2 sets ordered for patient. Older set for 5/12/11 was implanted instead of the correct set dated 6/10/11 leading to an underdose.

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Causes

- Another ME involved an ABORTED PROCEDURE
  - AU aborted procedure after 8 seeds implanted because anatomy precluded adequate placement of the lateral two columns of seeds. An ME due to underdose.

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Causes

- One case using Cs-131 was an overdose due to full treatment (114Gy) when prescription was for partial treatment (85Gy)

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Wrong Activity

- Overdose due to WRONG ACTIVITY – seeds ordered in air kerma but delivered in mCi
- Another overdose due to WRONG ACTIVITY entered into software (mCi instead of air kerma)

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Moving Seeds

- One underdose was attributed to seeds moving out of place
- Procedure done 10/7/2010 but ME identified 3/21/2011 when patient returned for post implant CT scan
  - >5 months later

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Multiple Patients

- 35 patients all at same facility:
  - 14 no Written Directive
  - 20 no post-implant dose recorded (17 of same patients with no post-implant CT)
- Program permanently suspended
- Authorized User MD removed from license

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Multiple Patients

- At another facility:
- 2 ME's were identified during a review of 12 cases done in 2008
- Both were overdoses based on D90
- "The NRC is reviewing this event and has not yet determined that it is a reportable medical event."
- In December 2008, the facility permanently terminated its prostate brachytherapy program; the last procedure was performed on 12/18/2008.

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Retracted Overdoses

- (Facility) conducted a comprehensive review of 44 prostate implant procedures performed since August 2003
- The overdose involved a D90 dose of 19,915 cGy (21.3%), which was administered on 11/13/2008
- The overdose event was **retracted** on 3/1/2011 after **a new post-plan was generated, which determined that the D90 value did not meet reportable criteria**.

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Retracted Overdoses

- Two Medical Events (involving four patients, all Pd-103) based on calculated underdoses to the prostate believed to be caused by prostate swelling
- These were later retracted after re-evaluations by the hospital's RSO and physicians concluded that the actual doses to the prostate were within 20% of the prescription.

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Retracted Overdoses

- During an on-site NRC inspection on 10/26/2010, two medical events were identified.
- Both events involved a delivered dose less than the prescribed dose following the implant of Pd-103 seeds for prostate therapy.
- Both events were **attributed to prostate swelling**. Corrective actions included procedure modification and personnel training.

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Retracted Overdoses

- During an on-site NRC inspection on 11/1/2010, two medical events were identified.
- Both events involved a delivered dose less than the prescribed dose following the implant of Pd-103 seeds for prostate therapy.
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Medical Events - §35.600 Gamma Knife: n=3

- Perfexion unit (event date of 6/2/11)
  - Prescribed 1,600 cGy to multiple lesions
  - Erroneous labeling of one of the tumor sites by physicist resulted in delivery of 85 cGy
  - The hospital suggested that Elekta make improvements to site identification.

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Medical Events - §35.600 Gamma Knife: n=3

- Equipment (model C 1.2/4C) malfunction on 10/25/2007 (reported to NRC 7/1/11)
  - The patient was prescribed 2,000 cGy/lesion to 10 brain lesions
  - Following treatment of 3rd lesion, couch failed
  - The physicist and neurosurgeon had to enter the room and manually pull the couch out of the unit
  - The unit contained a total activity of 3,011.7 Ci

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Medical Events - §35.600 Gamma Knife: n=3

- Model C (event date 11/14/11)
- Patient received <50% of prescribed dose due to mechanical failure
- The latch that fastens head frame to couch failed

Medical Events - §35.600 Remote Afterloaders, Teletherapy

	FY2010	FY2011
All §35.600	12	8
All HDR	9	7
Breast	2	4
Vaginal Cylinder	2	0
LDR remote afterloader	0	1
Gamma Knife	3	--
Teletherapy	0	0

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Medical Events - §35.600 HDR Brachytherapy Observations

No frequent problems

- 2 Lung treatments – both had problems with dwell position identification (but quite differently)
- 1 (2 patients) wrong length measured
- 1 Wrong transfer tubes
- 2 breast applicator problems – a balloon puncture and SAVI catheter split
- 1 treatment planning problem

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Medical Events - §35.600 LDR Remote-afterloading Brachytherapy Observations

1 biliary treatment where the catheter shifted during treatment

- 11/09/2010 - patient only received 124 cGy of the intended dose of 2,000 cGy during a biliary low dose rate (LDR) treatment using Ir-192

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§35.1000 Events

Total 11 reports

- SIR-Spheres: 3 reports, 2 events
- TheraSpheres: 8 events

Medical Events - §35.1000 Only Microsphere events

	FY2010	FY2011
All §35.1000	7	11
All Microsphere	4	11
SIR-Spheres	2	3 (1 pt related)
TheraSpheres	2	8
LDR remote afterloader	0	0
Perfection	2	0
Coronary	1	0

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§35.1000 Events

3 SIR-Spheres

- 1 Misread prescription
- 1 wrong artery (they intentionally tried a different route
- 1 patient, 1st fraction stasis, 2nd fraction stopped due to pain – This should not have been an event but agency said it was.

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§35.1000 Events

8 TheraSpheres

- 1 dose to wrong site (duodenum shunting)
- 1 wrong dose (high) due to error in ordering
- 5 wrong dose (low) due to technical problems (clumping (2), leaking, needle insertion into vial, defective catheter)
- 1 Wrong site when IR forgot which lobe was to be treated

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Radiopharmaceutical: Medical Event (No Written Directive Required)