



Byproduct Material Events Subcommittee Report

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Total number of procedures

- **(N = 1,098.8K)**
- **External Beam with SRS (Cranial Stereotactic Radiosurgery - Includes Gamma Knife Treatments) (2.9%)**
- **Brachytherapy - High Dose Rate Temporary Afterloading (3.0%)**
- **All other Cobalt Therapy <0.1% (<1%)**

Total number of procedures

- **Brachytherapy (LDR) Permanent Prostate Implants 1.9% (32%)**
- **Brachytherapy (LDR) Temporary Afterloading 0.4% (10%)**
- **Brachytherapy - High Dose Rate Temporary Afterloading 3.0% (34%)**
- **Radionuclide Therapy* 0.6% (17%)**

10 CFR 35.400

- **Brachytherapy - 25,272**
- **Permanent implant 20,877**
- **Prostate implant 20,877**
- **Other implant - -**
- **Temporary implant 4,395**

10 CFR 35.600

- **N = 42,587**
- **HDR** **32,964**
- **Teletherapy** **1,099**
- **GammaKnife** **8,524**

10 CFR 35.200

- **Diagnostic Imaging** **15,220,000**

Radionuclide w/ written directive [10 CFR 35.300]

- IMV Nuclear Medicine Report 537,400**
- IMV Radiation Therapy Report 6,593**
- Total 543,993**
- I-131 w/ written directive 531,700**
- I-131 thyroid imaging 445,000**
- I-131 thyroid therapy 56,200**

Radionuclide w/ written directive [10 CFR 35.300]

- I-131 other therapy 30,500**
- Sm-153 w/ written directive 1,900**
- Sr-89 w/ written directive 1,100**
- Other w/ written directive² 2,700**

Medical Events for Radiopharmaceuticals Requiring a Written Directive

- **Part §35.300 – 4 Medical Events**
 - **Radionuclide**
 - **I-131 (thyroid patients) - 3**
 - **I-131 MIBG (neuroblastoma patients) -1**

IMV Data 2007

- **Patients Treated with Radionuclide Therapy in Responding Departments**
– 92,400
- **Error Rate = 0.0000432**

§35.400 (2009)

- **Total = 26 Events (27 patients)**
 - **Contrasts with 10 Events involving 114 patients between 10/1/07 – 9/30/08**
 - **Y-90 microspheres: 9**
 - **Permanent prostate brachytherapy: 17 (one event from 2005 at DVA LA)**

§35.400 (2010)

- **Total = 26 Events (75 patients)**
 - **Y-90 microspheres: 5 (1 with 2 events in same pt); 4 others underdosed**
 - **1 Cs-137 vaginal cylinder came out very early (76 rem to thigh)**
 - **Permanent prostate brachytherapy: 69 pts**

§35.400 (2010)

- **Total = 26 Events (75 patients)**
 - **Permanent prostate brachytherapy: 69 pts**
 - **8 Overdoses; 1 excess dose to normal tissues; 1 incorrect seed activity**
 - **One overdose retracted based on repeat post-implant dosimetry**

§35.400 (2010)

- **Rest were underdoses**
 - **2 underdoses retracted since not deemed to be true medical events**
 - **Gland swelled and upon re-evaluation, final dose was within 20%**

§35.400 (2010)

- **One D90 <1% but NOT a real ME since 39/41 seeds within target – all implanted within a few mm of “isoline”.**
- **“could have been placed in better location”**
- **Due to poor image quality**

35.400 Comments

- **Majority based on dose (e.g. D90) and number of seeds outside prostate**
 - **Would these be medical events if we used activity or source strength?**
 - **Many from earlier times but reported in this period**
 - ***MANY* more next year expected!**

35.400 Comments

- **Total permanent implant brachytherapy ~ 25,272**
- **26 Events (75 patients) in 2010**
- **$75/25,272 = 0.002967$ (0.297%)**
- **Permanent prostate brachytherapy: 69 pts**
- **Total ~20,877**
- **$69/20,877 = 0.0033$ (0.33%)**

Medical Events - §35.600

Remote Afterloaders & Teletherapy

	FY2009	FY2010
All §35.600	14	12
All HDR	7	9
MammoSite	2	2
Vaginal Cylinder	2	2
LDR remote afterloader	0	0
Gamma Knife	7	3
Teletherapy	0	0

§35.600 - HDR Medical Events

- **Nucletron HDR - 4 events
(M=Breast intracavitary)**
 - **Wrong catheter length entered (2M)**
 - **Software failure**
 - **Incorrect treatment-unit mode**
 - **Incorrect contours entered**

§35.600 - HDR Medical Events

- **Varian HDR – VariSource 4 events (N=Needles or Catheters; C=Cylinders)**
 - **Wrong length (N)**
 - **“Patient moved” more likely wrong length (C)**
 - **Cylinder shifted (C)**
 - **No information**

Medical Events - §35.600

Gamma Knife

- **Gamma Knife - 3 events**
 - **Incorrect coordinates (data entry)**
 - **Helmet moved**
 - **Frame not fastened tightly**
- **Perfexion – 2 events (Part 1000)**
 - **Wrong side**
 - **Hard-drive failure**

Medical Events - §35.600

Observations

- **Only one type of HDR error stood out:**
 - **Wrong length (3 of 4).**
- **Compared with the number of procedures:**
 - **HDR**
 - **9 failures/33,000 procedures = 0.027%**

Medical Events - §35.600 Observations

- GammaKnife

- 3 failures/20,000 procedures =
0.015%**

- Teletherapy

- 0 failure / ~1000 procedures**

§35.1000 Events Observations

- **Perfexion – 2 events discussed above**
- **Microspheres – 4 events / 1400 treatments**
 - = 0.3%**
 - TheraSphere® – 2**
 - SIR-Spheres® - 2**
- **Coronary – 1**

In Search of a Common Denominator

- **Problems with use of IMV surveys**
 - **IMV focus is a business perspective (includes FTE, etc)**
 - **Doesn't collect data by regulatory section, i.e. §35.300**
 - **IMV collects data based on practice site vs. a procedure**

In Search of a Common Denominator

- **Problems with use of IMV surveys**
 - **Not clear where I-131 NaI (2-4mCi) for a diagnostic metascan procedure or where I-131 Bexxar therapy is listed**
 - **Radiopharmaceutical therapy data was a composite of two years, 2007 (2008 Dx report) and 2009 (2010 Tx report).**

In Search of a Common Denominator

- **IMV data is valuable in providing a denominator that is “close enough” for demonstrating where we should focus further attention**
- **Unless there is a rash of similar events, further reviews should focus on §35.400-35.1000 only**

Brachytherapy in the USA is Very Safe but...

2004

- **192,102 prostate cancer treatments**
- **41,790 prostate cancer treatments with permanent prostate implants (22%)**

Brachytherapy in the USA is Very Safe but...

2009

- **219,760 prostate cancer treatments**
- **17,490 prostate cancer treatments with permanent prostate implants (8%)**

Brachytherapy in the USA is Very Safe but...

- **Sources:**
- **IMV Radiation Therapy Benchmark Report 2004**
- **IMV Radiation Therapy Benchmark Report October 2010**