



Status of Medical Events FY 2015

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Medical Events

The dose threshold for diagnostic events precludes reportable events most years.

Each year there are approximately 150,000 therapeutic procedures performed utilizing radioactive materials.

- 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.
- 35.300 Use of unsealed by product material for which a written directive is required.
- 35.400 Use of sources for manual brachytherapy.
- 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.
- 35.1000 Other medical uses of byproduct material or radiation from byproduct material.



Medical Events 2015

46 Medical events reported - FY 2014

57 Medical events reported - FY 2015

	FY14	FY15
35.200	1	3
35.300	3	8
35.400	5	9 (10)
35.600	10	17
35.1000	27	20 (31)



Medical Events 2015

35.200 Medical events 3

Technetium-99m 2

- Administered entire 118 mCi multi dose vial to a single patient - 5.6 cGY (rad) whole body.
- Administered entire 160 mCi multi dose vial to a single patient - 7.8 cGY (rad) whole body.

Sodium Iodine I-123 1

- Administered 136.53 MBq (3.69 mCi) prescribed 11.1 MBq (300 µCi) I-123 for a thyroid uptake study.
- Thyroid exposure of 536 mGy (53.6 rad).
  - Physician's asked for correct dosage but Technologist ordered wrong dosage.
  - Potential contributor - scheduling diagnostic procedure in therapy time slot contributed.

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35.300 Medical events 8

Iodine 124 1  
 Iodine 131 6  
 Radium 223 1

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Iodine-124 1

- Administered 1.74 mCi - intended 3.25 mCi.
- Pediatric monoclonal antibody.
  - Intravenous connector leaked but not visually obvious.

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Iodine-131 6

- Administered 50 mCi instead of 35 mCi.
  - Patient had low Glomerular filtration Rate score.
  - 2 physicians ordered 2 different dosages both sent to facility wrong one (non-corrected) was selected.
- Administered 30.8 mCi instead of 3 mCi.
  - Written directive was wrong - delivered intended dose.
  - Authorized user complete the authorization section in its entirety prior to administration and peer review.

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### 35.400 Medical Events

Prostate ( 9 patients) 8  
Identified during inspection

- ☐ 2 patients with Pd-103 implants.
  - irregularities with one authorized user's (AU's) practices.
  - 37.6% and 66.9% of prescribed dose.
- ☐ 73% of prescribed dose.

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### 35.400 Prostate Events (cont.)

Partial Dose intended but full dose given

- ☐ Administered 16,000 cGy (rad) instead of 10,700 cGy (rad), 49.5% greater.
  - Human error - confirm and document the intended implant dose when the implant is scheduled.

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### 35.400 Prostate Events (cont.)

Delivered different from ordered activity

- ☐ Administered 18,432 cGy (rad) instead of 14,400 cGy (rad).
  - Air kerma ordered but not prescribed in air kerma.
- ☐ Administered 2.95 GBq (79.74 mCi) intended 3.796 GBq (102.6 mCi).
  - Did not recognize the difference between the delivered and the ordered activity.

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### 35.400 Prostate Events (cont.)

Wrong site - poor /uncalibrated ultrasound

- ☐ 30% of the seeds were implanted outside the treatment site.
- ☐ All 53 seeds were implanted into the penile bulb with dose of to this unintended area of 10,800 cGy (rad).


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 **35.400 Prostate Events (cont.)**

**Wrong site**


- Twenty of the seeds (29% of the total prescribed) were implanted into the bladder.
  - Enlarged median lobe of prostate protruding into the bladder.
  - Procedure modification and personnel training.

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 **Medical Events 2015**


35.600 Medical events	17
HDR	16
<input type="checkbox"/> Not specified	1
<input type="checkbox"/> Nose	1
<input type="checkbox"/> Gynecological	11
<input type="checkbox"/> Breast	3
Gamma knife	1(8)

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 **35.600 Medical events**

HDR	16
<input type="checkbox"/> Wrong Patient	1
<input type="checkbox"/> Error/Bad treatment plan	3
<input type="checkbox"/> Wrong Site	7
<input type="checkbox"/> Source fell out	1
<input type="checkbox"/> Physicist error	2
<input type="checkbox"/> Equipment problem/failure	2

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 **35.600 HDR Events**

- Not specified 1
  - Wrong Patient
    - Treated Patient with another's treatment plan.
    - Patient received 18% less dose than prescribed.
    - Retrained on the requirement to verify the patient's identity prior to treatment.

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### 35.600 HDR Events (cont.)

Nose 1

- ☐ Administered 6,850 cGy (rad) instead of 4,000 cGy (rad) 71% higher than written directive.
  - Junior physicist developed deficient treatment plan.
  - Reviewed by the authorized medical physicist and the authorized user.

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### 35.600 HDR Events (cont.)

Gynecological 11

Wrong site 7

- ☐ Outer vaginal mucosa and upper thigh received entire dose.
  - Applicator improperly placed and the source placed inferior to the treatment site and exterior to the opening of the vagina.
  - Vaginal burning.

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### 35.600 HDR Events (cont.)

Wrong Site (continued)

- ☐ Outer vaginal mucosa and upper thigh received the entire 2100 cGy - radiation burns.
  - Source inferior to the treatment site and exterior to the opening of the vagina.
  - Contributor – poor film quality due to obesity - thought it showed proper placement.

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### 35.600 HDR Events (cont.)

Wrong Site (continued)

- ☐ 2 skin (0.5 cm wide and 1 cm long) radiation burns on both upper thighs.
  - patient's skin dose calculated to be 4,000 cGy (rad) at a depth of 0.2 cm.
  - 33% less dose to the intended site than prescribed by the written directive.
  - Either assembled the vaginal cylinder applicator incorrectly or it became loose while in the patient.

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### 35.600 HDR Events (cont.)

#### Wrong Site (continued)

- Fractional dose of 450 cGy delivered to wrong site.
  - Physician had difficulty inserting applicator due to edema and tenderness.
  - Previous weeks post treatment images, showed the applicator was not where it was supposed to be.
  - Approximately 7 cm short of the intended position

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### 35.600 HDR Events (cont.)

#### Wrong Site (continued)

- 260 cGy (rad), the second fractional dose, delivered to 1 cubic centimeter of skin on the right upper thigh.
  - Close-ended catheter was not fully seated inside the vaginal cylinder.
  - Positioned approximately 15 cm proximal from the prescribed treatment position.
  - Now must verify the position of the cylinder and the length of the transfer tube catheter.

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### 35.600 HDR Events (cont.)

#### Wrong Site (continued)

- Tissue 3 cm in length inferior to the treatment site received 400 cGy (rad).
  - Post-treatment imaging revealed the cylinder applicator had come loose from the holder and shifted 3 cm.
  - A resident and physician must now verify applicator immobilization prior to administration and reduce the time from applicator placement in the patient to administration.

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### 35.600 HDR Events (cont.)

#### Wrong Site (continued)

- Treatment site received 20 % of intended dose.
  - Inserted the vaginal cylinder 3 cm distal to the vaginal cuff (intended treatment site).
  - Always use all four segments of the treatment cylinder and instructing staff to pay close attention to patient movement.
  - Additional imaging of cylinder placement also to be required.

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### 35.600 HDR Events (cont.)

#### Source fell out 1

- ▣ Administered 1,200 cGy (rad) instead of 1,800 cGy.
  - Physicist entered room and found the cylinder on the treatment table.
  - Failure to secure the cylinder in place and the inability to view the cylinder on the camera.

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### 35.600 HDR Events (cont.)

#### Physicist error 2

- ▣ Administered 1,500 cGy (rad) during the three fractions instead of 900 cGy (rad).
  - Physicist inadvertently selected and delivered an incorrect treatment plan of 900 cGy (rad) per fraction for the third fraction.
  - Skipped "best practice" step of verifying the treatment plan.

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### 35.600 HDR Events (cont.)

#### Physicist error (cont.)

- ▣ Administered 700 cGy (rad) during one of three fractions instead of 400 cGy (rad).
  - Physicist loaded the patient's plan into the treatment control station, but then loaded another patient's treatment plan for review.
  - The physicist verbally verified the patient's information from memory, not from the computer screen containing the other patient's treatment plan.

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### 35.600 HDR Events (cont.)

#### Equipment problem 1

- ▣ Administered 105 cGy (rad) during second fraction instead of 1050 cGy (rad).
  - Two AMPs engaged emergency stop, terminated treatment, and retracted the source to the shielded position.
  - On restart, the treatment countdown time was increasing, not decreasing.
  - Console indicated treatment terminated but source extension warning light was activated.

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### 35.600 HDR Events (cont.)

#### Breast (Savi) 3

- ☐ 13,000 cGy (rad) to an unintended site – incision site.
  - Patient returned with pain and redness at the incision site of the left breast.
  - 21 cubic centimeters of tissue surgically excised.
  - Suspended treatments to investigate.
  - Considering using of a second physicist for independent evaluation of the treatment plan and the a written check-off form.

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### 35.600 HDR Events (cont.)

#### Breast (Savi) continued

- ☐ Administered 13,000 cGy (rad) to entrance site 3 cm from treatment site - tissue would not heal mastectomy performed.
  - Dose delivered to connector end and not the tip end.
  - Dwell positions within the applicator were not accurately reconstructed in the treatment planning computer.
  - Difficulty identifying the starting position for multiple catheter HDR treatments within the system.

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### 35.600 HDR Events (cont.)

#### Breast (Savi) continued

- ☐ Administered 60 cGy (rad) instead of 340 cGy.
  - Friction event occurred while sending out the check cable in the third channel and the HDR unit was unable to fully retract the check cable.
  - Faulty check cable revealed a fray approximately 0.5 cm behind the welded junction.
  - Total of 3 check cables had similar fraying.

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### 35.600 Medical Events

#### Gamma knife (Model Type C) 1

- ☐ Administered 8.8 % more to treatment site and 71 cSv (71rem) to wrong site.
  - 16 gamma knife collimators were placed where there should have been plugs prior to patient treatment.
  - Page three of the written directive which had the plug information was absent during equipment preparation.
  - Move plug use to first page of the written directive.

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### Medical Events 2015

35.1000 Medical events (31 patients) 20

Perflexion (8 patients)	1
I-125 Seed localization	1
Y-90 Microspheres	18
Therasphere® (12 patients)	8
SirSphere®	10

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### 35.1000 Medical Events

Perflexion (8 patients) 1

8 patient administrations meet definition of medical event and may also meet abnormal occurrence criteria.

- Approximately 1.87 mm off target misalignment of the patient positioning system due to maintenance/service.
- Elekta evaluating service issue.

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### 35.1000 Medical Events

I-125 Radioactive seed localization 1

Administered 83.6 cGy (rad), instead 18.4 cGy (rad).

- Due to illness, the patient was unable to return in 5 days and did not have seeds removed until 26 days after implantation.
- Programmatic review identified other patients did not have their seeds removed until later than the 5 days but did not reach criteria for medical event reporting.

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### 35.1000 Medical Events

Y-90 Microspheres (22 patients) 18

Therasphere® (12 patients) 8

- Multiple patients (5) 1
- Wrong site 1
- Low flow rate –arteries 1
- Kink 1
- Radiation detector 2
- Remained in vial/tubing 2

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Therasphere®

- 5 patients administered less than 80% of prescribed dose.
  - Excess dose found in hub of catheters - all patients treated with smaller catheters.
- Administered 874 MBq (23.62 mCi) to wrong lobe of liver.
  - Intended for left lobe delivered to right lobe.
  - Injected microspheres into wrong artery.

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Therasphere® (continued)

- Administered 588 MBq (15.89 mCi) instead of 763 MBq (20.62 mCi).
  - Size and physical condition of the patient's arteries caused a low flow condition during treatment.
- Administered 5,220 cGy (rad) instead of 14,700 cGy (rad) to segment 6 to wrong lobe of liver.
  - Kinking was noted at the junction of the rigid hub.

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Therasphere® (continued)

- Administered 62% of intended 15,000 cGy (rad).
  - After "completion of procedure" Rados detector erroneously indicated 0 mR/hour in delivery system.
  - Microspheres left in vial.
- Administered 60% of intended 12,000 cGy (rad).
  - Problems with Rados detector contributed to event.
  - Activity concentrated at plunger attached to vial.


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Therasphere® (continued)


- Administered 84 Gy (8,400 rad) instead of 12,500 cGy (rad).
  - Microspheres were trapped in the vial for an unknown reason.
- Administered 9,815 cGy (rad) instead of intended 12,000 cGy (rad).
  - Most of dose remained in D-line tubing with, with lesser amounts in micro-catheter and vial.

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SirSphere®	10
- Wrong site	4
- Error in Calculation	1
- Delivery system issue	2
- Operator error	1
- Clumping/Occluded	2

- SirSphere® Wrong Site 4
-  Kidney – renal artery
- Facility's first Y-90 microsphere patient and the manufacturer's representative was present.
  - Dose to the kidney calculated by the manufacturer to be 1,345 Gy (134,500 rad).
  - Formal written checklist completed prior to each administration, additional mapping images available for placement of the catheter, and second physician review of the catheter placement.

Wrong Site (continued)

-  Stomach
- Administered 1.36 GBq (36.76 mCi) to liver instead of 2.12 GBq (57.4 mCi) but reached stasis.
  - Post-treatment scans indicated microspheres in stomach.
  - Calculations determined that the stomach contained 0.011 GBq (0.3 mCi) of Y-90 for a dose of 54.7 cSv (rem).

Wrong Site (continued)

-  Small Bowel
- Intended dose of 7,800 cGy (rad) to the liver.
  - Physician felt that the microspheres were not traveling to the liver and discontinued treatment.
  - Small bowel received a dose of 3,600 cGy (rad).

Wrong Site (continued)

Wrong liver site

- Administered 7,750 cGy (rad), instead 6,450 cGy (rad) posterior portion of the right lobe.
  - Received administration intended for the anterior portion of the right lobe of the liver.
  - Color coding procedure failed to prevent the incident will discontinue use of color coding dual doses.
  - Permit only one dosage of microspheres in the interventional radiology at a time.

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Dose calculation error 1

- Administered 1.37 GBq (37.03 mCi) instead of 1.09 GBq (29.43 mCi).
  - Physician prescribed activity based on a 20% reduction due to the lung shunt volume.
  - Both the pre-reduction and post-reduction activity values appeared in the written directive.
  - Activity calculations based on the pre-reduction value.

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- Administered 974.95 MBq (26.35 mCi) instead of 1.23 GBq (33.26 mCi).
  - Administration terminated - air bubbles were collecting in the tubing delivering the microspheres.
  - Microsphere delivery kit was set up incorrectly.
  - Air entered the device from an uncovered needle.
- Administered 384.8 MBq (10.4 mCi) instead of 658.6 MBq (17.8 mCi).
  - Administering device came apart during the procedure - microspheres were lost in the apparatus.

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- 42% of dose delivered.
  - During setup, patient's catheter disconnected to flush out potential air bubble.
  - Started administration without realizing that the line was still disconnected.
- 78.1% of dose delivered.
  - Clumping in the tubing near the 3-way stopcock.
  - Manufacturer determined cause was abnormally high concentration of microspheres being administered.

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### 35.1000 Y-90 Events (cont.)

- 52% of dose delivered.
- Physician concluded catheter was clogged when the injection of microspheres through the delivery system met with considerable resistance.
- Lost some microspheres when catheter disconnected.
- Manufacturer review of the equipment suggested that blood in the catheter caused the catheter to clog and was an indication that the catheter was not sufficiently flushed prior to infusion.

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### Acronyms

- AMP – Authorized Medical Physicist
- AU – Authorized User
- cGy – centiGray
- FY – Fiscal Year
- GBq – Giga Becquerel
- HDR – High Dose Rate Remote Afterloader
- I-131 – Iodine-131    I-124 – Iodine-124
- mCi – millicurie     $\mu$ Ci – microcurie
- MBq – Mega Becquerel
- Pts - Patients
- Y – Yttrium

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QUESTIONS?

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