U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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.

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.

35.200 Medical events (cont.)

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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Medical Events 2015

35.300 Medical events 8

Iodine 124 1
Iodine 131 6
Radium 223 1

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35.300 Medical Events

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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35.300 Medical Events (cont.)

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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35.300 Medical Events (cont.)

- **Administered 1.57 mCi instead of 2 mCi.**
  - Discovered during routine audit.
  - 2 independent measurements and review of dose to ensure it is within 20%.
- **Administered 142 mCi instead of 30 mCi.**
  - Wrong patient – misidentified the patient.
- **Administered 75 mCi instead of 150 mCi.**
  - Dose supplied as 2 capsules only one given.

35.300 Medical Events (cont.)

Ra-223 dichloride 1

- Administered 206 microcuries (µCi) instead of 108 µCi.
- Technologist misread the prescribed dose and injected 2 dosages instead of the 1 prescribed.
- Corrective action - 2 technologists verify patient information and prescribed dose.

Medical Events 2015

35.400 Medical events 9

Tongue	1
Prostate (9 patients)	8

35.400 Medical Events

Tongue Ir-192 1

- 2 ½ hours after linens changed oncologist determined that one strand missing.
- Strand found in the linen basket, recovered, reinserted - tongue received the intended dose.
- Worst-case skin exposure to the patient of 51.75 cSv (rem).

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

- Not specified 1
- Nose 1
- Gynecological 11
- Breast 3

Gamma knife 1(8)

18

35.600 Medical events

HDR **16**

- Wrong Patient 1
- Error/Bad treatment plan 3
- Wrong Site 7
- Source fell out 1
- Physicist error 2
- 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.

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.

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.

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.

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.

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.

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.

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.

35.600 HDR Events (cont.)

Breast (Savi) 3

- **3,000 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.

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.

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.

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.

Medical Events 2015

35.1000 Medical events (31 patients) **20**

Perfexion (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

Perfexion (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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35.1000 Y-90 Events

Therasphere®

- **5 patients administered less than 80% of prescribed dose.**
  - Excess dose found in hub of catheters **- a**ll 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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35.1000 Y-90 Events (cont.)

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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35.1000 Y-90 Events (cont.)

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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35.1000 Y-90 Events (cont.)

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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35.1000 Y-90 Events (cont.)

SirSphere® 10

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

35.1000 Y-90 Events (cont.)

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 imagines available for placement of the catheter, and second physician review of the catheter placement.

35.1000 Y-90 Events (cont.)

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).

35.1000 Y-90 Events (cont.)

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).

35.1000 Y-90 Events (cont.)

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.

35.1000 Y-90 Events (cont.)

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.

35.1000 Y-90 Events (cont.)

- **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.

35.1000 Y-90 Events (cont.)

- **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.

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.

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 µCi – microcurie
- MBq – Mega Becquerel
- Pts - Patients
- Y – Yttrium

QUESTIONS?