

Status of Medical Events FY 2016

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1

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.

2

Medical Events 2011-1312

- 58 Medical events reported - FY 2011
- 48 Medical events reported - FY 2012
- 43 Medical events reported - FY 2013

	<u>FY11</u>	<u>FY12</u>	<u>FY 13</u>
35.200	3	2	0
35.300	6	2	2
35.400	26 (2?)	15	15
35.600	12	13	10
35.1000	11	20	16

3

Medical Events 2014-16

- 46 Medical events reported - FY 2014
- 57 Medical events reported - FY 2015
- 50 Medical events reported - FY 2016

	<u>FY14</u>	<u>FY15</u>	<u>FY16</u>
35.200	1	3	4
35.300	3	8	4
35.400	5	9(10)	6(18)
35.600	10	17	6
35.1000	27	20(31)	30

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Medical Events 2016

35.200 Medical events 4

Technetium-99m

- Administered entire 128 milliCurie(mCi) multi dose vial to a single patient - 8 centiGray (cGY) (rad) whole body.
 - Staff member failed to verify dosage.
 - Licensee will no longer prepare kits.
- Intra venous port leaked.
 - Skin exposure exceeded 50 centiSievers(cSV)(rem).

5

Medical Events 2016

35.200 Medical events (cont.)

- Failure to verify dosage or type of procedure.
 - Prescribed 18.5 to 37 MegaBequerel (MBq) (0.5 to 1 mCi) filtered sulfur colloid for a lymphoscintigraphy study.
 - Technologist delivered 88.8 MBq (2.4 mCi) unfiltered sulfur colloid for a gastric emptying study.
 - Potential dose of 58.08 to 273.6 cSv (rem) to the skin.
 - Technologist now has to verbally confirm the activity and type of procedure with the doctor prior to administration.

6

Medical Events 2016

35.200 Medical events (cont.)

- Wrong patient and wrong drug.
 - Prescribed interstitial 18.5 MBq (0.5 mCi) Tc-99m for sentinel node scintigraphy.
 - Received interstitial 1,110 MBq (30 mCi) Tc-99m bone.
 - Miscommunication contributed to error.
 - Technologist failed to verify patient identity was same as on the dosage pig

7

Medical Events 2016

35.300 Medical events 4

Samarium 153	1
Radium 223	2
Iodine 131	1

8

35.300 Medical Events

Samarium 153

1

- Administered 3.22 GBq (86.9 mCi) – instead of 2.48 GBq (67.13 mCi).
 - Dosage from pharmacy was not correctly calculated for the patient's weight.

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35.300 Medical Events (cont.)

Ra-223 dichloride

2

- Administered 119.3 microcuries (μCi) instead of 86.7 (μCi).
 - Wrong patient.
- Administered 99.4 μCi instead of 980 μCi .
 - Failed to observe the difference between the calibrated activity and the prescribed activity.
 - Licensee believes authorized user intended to prescribe 98 μCi a typical dosage.
 - Corrective action - list the activity in μCi , instead of mCi.

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35.300 Medical Events (cont.)

Iodine-131

1

- Administered 53 mCi instead of 120.8 mCi.
 - Dosage delivered in two capsules.
 - One capsule returned to the pharmacy.
 - Licensee to revise procedures for transfer of radioactive materials.

11

Medical Events 2016

35.400 Medical events

6

Gynecological	1
Prostate (18 patients)	5

12

35.400 Medical Events

Gynecological

1

- Administered 1,500 cGy (rad) - instead of 3,460 cGy (rad) to the treatment site.
 - Crimped applicator tube in lead pig during transport.
 - Incorrectly interpreted resistance during application placement in left side of tandem as indicating source was at end tube.
 - Lower rectum and vaginal areas received more dose than expected.

13

35.400 Medical Events (cont.)

Prostate (18 patients)

5

One licensee 2 event reports 15 patients.

- 2006 - 2011 - **13 patients** - identified by inspectors
 - Administered dose differed by more than 50 cSv (rem) and by 20% or more.
- 2016 – **2 patients** identified by post implant images)
 - Administered 8,319 cGy - 66.55% of prescribed dose.
 - Administered 8,906 cGy (rad) - 71.25% of prescribed dose.

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35.400 Prostate Events (cont.)

- **Ultrasound the images confusing.**
 - No activity administered to the prostate gland.
 - Seeds mistakenly implanted into a mass identified as the prostate gland.

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35.400 Prostate Events (cont.)

Human error.

- Administered 643.948 MBq (17.404 mCi) for a dose 69.55% to the intended target tissue.
- Administered total seed activity of 26.34 mCi in prostate for dose of 59.79% intended 45.33 mCi.

16

Medical Events 2016

35.600 Medical events	6
HDR (8 patients)	6
• Broncus (3 patients)	1
• Mandible	1
• Gynecological	2
• Prostate	2

17

35.600 HDR Events

Bronchus (3 patients) 1

- **Adaptor piece used to determine Dwell positions.**
 - 2 of 3 fractions delivered 4 cm from treatment site- no dose to treatment site for 2 fractions.
 - 3 of 3 fractions delivered to wrong treatment site - received 0%, 43% and 20 % of dose to treatment site.
 - 3 of 3 fractions to wrong treatment site no dose to treatment site.
 - Revise HDR bronchoscopy treatment procedure.
 - ELEKTA update user's manual, put warning sticker on the applicator packaging, and improve user training.

18

35.600 HDR Events (cont.)

Mandible 1

- **Wrong Patient Treatment Plan.**
 - Used treatment plan time for another patient - 8.2 seconds less.
 - "time-out" policy to confirm the patient and treatment information is correct prior to treatment.

19

35.600 HDR Events (cont.)

Gynecological 2

- **Wrong site.**
 - **Patient reported to primary care physician with skin burns on leg.**
 - Thought second of three fractions delivered 6,000cGY rad to leg.
 - Human error with the transfer tube/applicator interface.

20

35.600 HDR Events (cont.)

Gynecological cont.

Equipment Problem.

- **Prior to third channel, friction detected in the applicator check cable, the check cable withdrawn, and the treatment stopped.**
 - Prescribed 600 cGy (rad) during the tandem and ovoid treatment.
 - Applicator permanently removed from use.

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35.600 HDR Events (cont.)

Prostate

2

• Equipment Failure.

- Patient received .16% of intended 1,350 cGy.
- Error code 4 (friction was detected during source in-drive) on second of 18 catheter sites, the source retracted, unit reset, but problem persisted.
- Several parts required replacement (opto-pair interface, power supply control board, and stepper motor control board).

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35.600 HDR Events (cont.)

Prostate continued

• Equipment Failure.

- During second fraction on catheter site 10 of 19 catheter sites, multiple error codes (source had moved from the dwell position and that a reset of the console was required and friction was detected during source in-drive).
- Console reset but attempts to continue the treatment failed and treatment terminated at 12.5 % of dose.
- V-block and opto-pair had to be replaced.

23

Medical Events 2015

35.1000 Medical events

30

Perfexion

3

I-125 Seed localization

1

Y-90 Microspheres

26

Therasphere® 13

SirSphere® 13

24

35.1000 Medical Events

Perflexion

2

- **Wrong treatment site - new frame adaptor issue.**
 - Patient was given a break and the frame adapter was observed locked, but in wrong position.
 - Displacement was a maximum of 2 cm in one plane.
- Non-keyed design - frame adaptor could be placed onto the head frame incorrectly.
- Difference in clamping force between the old and new frame adapters.
- Operator did not follow new instructions.

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35.600 Medical Events

Perflexion cont.

- **Estimated Administration of 930 cGy (rad) to an unintended cerebral site, with a volume of 0.7 cc.**
 - Treatment stopped after 15 of 16 sites to re-sedate the patient.
 - On site 16, the patient awoke and moved significantly.
 - The frame was out of position when the patient was removed from the unit.
 - Frame could have moved during or after treatment.

26

35.1000 Medical Events

Perflexion cont.

- **Human error – incorrect positioning of isocenter.**
 - Administered 8,500 cGy to left side of the brain instead of right side of brain.
 - Identified as the treatment was completed.
 - Corrective actions - procedure modifications.

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35.1000 Medical Events

I-125 Radioactive seed localization. 1

- **Seed unable to be removed on schedule.**
 - Surgery was cancelled - patient had a stroke during interim days.
 - Initial estimates of the patient's effective whole body dose are 3.7 cSv (rem) and 73 cGy (rad) to the breast..

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35.1000 Medical Events

Y-90 Microspheres 26

Therasphere® 13

- Wrong site 2
- Volume determination 1
- Catheter 1
- Radiation detector 3
- Modified apparatus 1
- Unusual resistance 2
- Remained in waste/delivery 2
- No description/reason 1

29

35.1000 Y-90 Events (cont.)

Therasphere® wrong site 2

- **administered to previously treated segment IV (left lobe) not segments V, VI, VII, and VIII (right lobe).**
- Concluded catheter moved from patient movement or breathing but did not perform fluoroscopic contrast imaging immediately prior to treatment to verify catheter position.
- Medical consultant determined that segment IV received 43,700 cGy (rad) - hepatic and tumor necrosis are anticipated.

30

35.1000 Y-90 Events (cont.)

Therasphere® wrong site(cont.)

- **Administered 88.6% more than prescribed –dosage intended for another patient the next day.**
- wrong lobe because of displaced the catheter and failure to verify its position during administration.
- Inadequate procedures and insufficient training.
- Additional imaging techniques to verify catheter placement.

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35.1000 Y-90 Events (cont.)

Therasphere® volume determination 1

- **Administered 9,400 cGy (rad) instead of intended 12,000 cGy (rad) to entire left lobe of the liver.**
- Tc-99m image taken prior to the administration showed a smaller liver volume that was used to determine the amount of Y-90 to administer.
- Change work flow so a second review of the liver volume is performed prior to administration.

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35.1000 Y-90 Events (cont.)

Therasphere[®] catheter 1

- Administered 0.491 GBq (13.27 mCi) instead of 3.1 GBq (83.78 mCi).
 - Post apparatus readings were higher than expected.
 - Most of the activity remained within the catheter.
 - Catheter representative thought catheter apparatus may not have been fully extended.
 - Will use a different and newer catheter product.

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35.1000 Y-90 Events (cont.)

Therasphere[®] radiation meter 3

- Administered 64% of 3,065.45 MBq (82.85 mCi).
 - Electronic dosimeter attached to the treatment device had fluctuating readings but no low battery warning.
 - Dosimeter readings indicated microspheres were administered but 36% of the activity remained.
 - Dosimeter checked and had low battery warning.
 - Corrective actions - changing batteries in the electronic dosimeter prior to each administration.

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35.1000 Y-90 Events (cont.)

Therasphere[®] radiation meter cont.

- Administered 71% of 14,000 cGy (rad).
 - Stasis was not reached, radiation survey meter revealed 0 reading and it was thought the patient received the entire dose.
 - From waste measurements, and calculations 4,000 cGy (rad) were discovered in the waste.

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35.1000 Y-90 Events (cont.)

Therasphere[®] radiation meter cont.

- Administered 62% of 1.81 GBq (48.92 mCi).
 - At completion radiation survey revealed 0 mR/hour.
 - Microsphere delivery kit taken to the hot laboratory for further radiation surveys and had 34% of dose in vial.

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35.1000 Y-90 Events (cont.)

Therasphere[®] modified apparatus 1

- **Administered 52% of 819.18 MBq (22.14 mCi).**
 - Authorized user observed air in the delivery system and added a three-way stopcock to the system to collect the air.
 - Radiation surveys revealed 0 mR/hour from the dose vial, but significant activity found in plastic container.
 - Concluded the three-way stopcock interfered with the administration.

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35.1000 Y-90 Events (cont.)

Therasphere[®] unusual resistance 2

- **Administered 25% of activity during two separate administrations.**
 - Unusual resistance during the both procedures.
 - Unsuccessful attempts to clear the line, efforts to complete the administration were experienced both times and the administrations were terminated.
 - Delivery sets from the same lot and both doses of microspheres came from the same lot.

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35.1000 Y-90 Events (cont.)

Therasphere[®] unusual resistance cont.

- **Administered 76% of intended 12,500 cGy (rad).**
 - Resistance in the tubing felt during administration .
 - The tubing disconnected, flushed with saline solution, and then reattached.
 - 24% of radioactivity was in the waste.

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35.1000 Y-90 Events (cont.)

Therasphere[®] waste/delivery 2

- **Administered 50% of activity.**
 - Discovered at completion of dose assessment - primarily in the system waste container.
- **Administered 74% of activity.**
 - Discovered at completion of dose assessment - primarily in delivery equipment.
 - Attributed to human error - corrective actions included providing new training to personnel.

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35.1000 Y-90 Events (cont.)

Therasphere® no description/reason

- Administered 0.28 GBq (7.57mCi) 15% of intended 1.87 GBq (50.54 mCi).

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35.1000 Y-90 Events (cont.)

SirSphere® 13

- Dose Calculation Error 2
- Wrong site 1
- Apparatus tubing 1
- Catheter Clumping/Occluded 3
- Catheter displaced 1
- Vials 4
- No description/reason 1

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35.1000 Y-90 Events (cont.)

SirSphere® Dose calculation error 2

- Administered 643.8 MBq (17.4 mCi) instead of 499.5 MBq (13.5 mCi).
 - 29% more than prescribed .
 - Technologist miscalculated the dosage required.
- Administered 77 % to 78 % of intended dose.
 - Authorized User forgot to change the lung and liver estimated doses on the pre-calculation worksheet.
 - Instructions to draw slightly more microspheres than prescribed to account for the 74 MBq (2 mCi) in waste.

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35.1000 Y-90 Events (cont.)

SirSphere® Wrong Site 1

- Delivered to left lobe instead of right.
 - Intended 1,076.7 MBq (29.1 mCi) for right lobe.
 - Administering 868.76 MBq (23.48 mCi) to left.
 - 119.4% of the activity prescribed in the written directive scheduled.
 - Failure to follow procedures.

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35.1000 Y-90 Events (cont.)

SirSphere® apparatus tubing 1

Administered 0.74 GBq (20 mCi) instead of 0.95 GBq (25.7 mCi).

- A large amount of microspheres found in the tubing.
- No resistance felt - stasis not reached.
- Long time period between microsphere preparation and patient administration contributed to the cause.
- Will draw 4 to 6% more activity in dose to account for decay and residual activity in the apparatus tubing.

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35.1000 Y-90 Events (cont.)

SirSphere® catheter Issues 3

• Administered 0.04 GBq (1.08 mCi) 3% of intended 1.29 GBq (34.86 mCi).

- Encountered back pressure and terminated the procedure.
- Microsphere clumping.
- Improper manufacturer preparation of microspheres, occlusion of the micro-catheter used, or collection of air in the three-way stopcock.

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35.1000 Y-90 Events (cont.)

SirSphere® catheter displaced

• Administered 518 MBq (14 mCi) 56% of 925 MBq (25 mCi).

- Microspheres ended up in the patient's catheter, chucks, and on the floor.
- Attributed to patient movement that displaced the catheter in the patient and disabling treatment to the desired liver lobe.
- When patient moves during treatment, will stop the administration.

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35.1000 Y-90 Events (cont.)

SirSphere® catheter issues cont.

• Administered 70% activity.

- Concluded caused by a clogged catheter.
- Administered 144.3 MBq (3.9 mCi) 33% of intended 432.9 MBq (11.7 mCi).
- Significant resistance within the Surefire microcatheter.
- Low flow in catheter or target vessels may allow distal accumulation of microspheres in catheter.
- Use vasodilators will be administered prior to infusion.

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35.1000 Y-90 Events (cont.)

SirSphere ® vial issues

4

- **Administered 129.5 MBq (3.5 mCi) 44% of intended 296 MBq (8 mCi).**
 - Small plug of microspheres was noticed in the bottom of the dose vial.
 - Lack of experience with microspheres.
 - Mixing the dose as close as possible to the delivery time, routine agitation of vial, adjusting position of the inlet tubing needle to ensure maximum agitation.

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35.1000 Y-90 Events (cont.)

SirSphere ® vial issues cont.

- **Administered 268.25 MBq (7.25 mCi) 69% of intended 389.98 MBq (10.54 mCi).**
 - Residual activity adhered to top of vial.
 - Either the needle not inserted far enough into the vial or agitation of the vial during the administration caused microspheres to adhere to the top of the vial.
 - Increase orders by 5% to compensate for residual activity that remains in vials and tubing.

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35.1000 Y-90 Events (cont.)

SirSphere ® vial issues cont.

- **Administered 492.1 MBq (13.3 mCi) 74% of intended 669.7 MBq (18.1 mCi).**
 - Residual activity in the vial.
- **Administered 10 % of intended dose.**
 - Puncture site in V-vial rubber stopper leaking.
 - Could not stop leak with dermabond (manufacturer recommended glue) - aborted procedure.
 - Radiopharmacy to higher gauge, smaller lumen needles.

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35.1000 Y-90 Events

SirSphere ® no description/reason

- **Administered 79.5% of their prescribed dose.**
 - 20.5% of dose found in device/waste.

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Acronyms

- 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
- μ Ci – microcurie
- MBq – Mega Becquerel

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QUESTIONS?

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Other Medical Byproduct Material Events FY 16

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ACMUI
April 26, 2017**

Other Medical Byproduct Material Events – identified in FY16

- **NMED event involving medical license or associated license**
- **NMED event associated with medical license, including § 35.3047 events**
- **Does not include § 35.3045 medical events or other patient safety events**

2

Other Medical Byproduct Material Events – identified in FY16 [FY15]

Categories

- **Miscellaneous – 8 [13]**
- **Leaking sealed sources – 8 [4]**
- **Lost mats/sources (no Cat. 1 or 2) – 17 [24]**
- **Shipping issues – 13 [12]**
- **Landfill alarms – 71 [114]**

3

Other Events – Miscellaneous FY16 [FY15]

- **Occupational overexposure – (4) 0 [6]**
- **Declared pregnant worker – 2 [0]**
- **§ 35.3047 events – 1 [1]**
- **Suspected public overexposure – 2 [0]**
- **Equipment failures – 1 [3]**
- **Contamination – 2 [2]**
- **Recordkeeping – 0 [1]**

4

Other Events –

Leaking sealed sources FY16 [FY15]

- Cs-137 source (<0.3 mCi) – 4 [0]
- Ge-68 source – 2 [0]
- I-125 source (localization) – 1 [2]
- I-125 source (eye plaque) – 0 [1]
- Pd-103 source (prostate seed) – 0 [1]
- Isotope not given – 1 [0]

5

Other Events –

Lost materials/sources FY16 [FY15]

- Lost after procedure (I-125) – 8 [10]
- Lost/found/lost and found – 7/0/0 [4/1/0]
- Buried pacemaker – 0 [1]

6

Other Events –

Shipping issues FY16 [FY15]

- Delivered issue – 3 [4]
- Stored in unsecured area – 0 [1]
- Accident – 1 [0]
- Shipping package issues – 6 [7]
- No license approval for receipt – 1 [0]
- Lost during shipment – 2 [8]

7

Other Events –

Landfill alarms FY16 [FY15]

Isotope	Hospital	Residence	Not identified
I-131	1 [6]	0 [10]	41 [58]
In-111	0 [1]	0 [2]	3 [1]
Tc-99m	3 [3]		11 [10]
Tl-201		0 [1]	0 [1]
Not identified			12 [21]

Reports from States or other areas –

10 [18]% AL 86 [81]% CA 0 [1]% DC 0 [1]% FL 4 [0]% TN

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Acronyms

- **ACMUI** – Advisory Committee on Medical Uses of Isotopes
- **FY** – NRC Fiscal Year (October 1-September 30)