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

Status of Medical Events FY 2014

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Medical Events 2014

- **43 Medical events reported - FY 2013**
- **46 Medical events reported - FY 2014**

	FY13	FY14
35.200	0	1
35.300	2	3
35.400	15	5
35.600	10	10
35.1000	16	27

2

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.

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Medical Events 2014

35.200 Medical events **1**

Technetium-99m

- Administered entire multi dose vial 140 mCi to single patient
  - 6-7 cGY (rad) whole body

4

Medical Events 2014

35.300 Medical events **3**

Samarium 153 1

- Administered 39 microcuries to skin of arm
- Intended 100 microcuries intravenously

Radium – 223 1

- Error in writing millicuries in written directive
- administered micro curies

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35.300 Medical Events

I-131 1

- 30 millicuries delivered to wrong patient
- Patient was given bracelet id of another patient
- Authorized User did not use another identifier to confirm the patient was correctly identified
- 728 cGy(rad) to the thyroid

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Medical Events 2014

35.400 Medical events **5**

Gynecological 1

Prostate 4

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35.400 Medical Events

Gynecological Cs-137 1

- Dislodged applicator
- Treatment time 49.5 hours – planned 63.1
- Treatment site received 78% of intended dose
- inner thighs received up to 1,509 cGy (rad) expected 652 cGy (rad).

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35.400 Medical Events

Prostate 4

- Air Kerma - received 18,400 cGy (rad) instead of the prescribed 14,500 cGy (rad) medical physicist mistakenly ordered using mCi instead of the air kerma value.
- Some seeds inadvertently implanted into the scar tissue - 54% of prescribed dose delivered to treatment site

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35.400 Medical Events

Wrong Site - Ultrasound Issues 2

- Seeds implanted 3.5 cm inferior from the target location 29.31% of the prescribed dose was delivered to the target tissue.
- 88 seeds were implanted in penile bulb 34 seeds prostate gland attending urologist mistook the penile bulb for the prostate gland

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Medical Events 2014

35.600 Medical events **10**

HDR 9

- Skin 2
- Bronchial 1
- Not designated 2
- Pelvic 1
- OBGYN 3

Gamma knife 1

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Medical Events 2013

35.600 Medical events

HDR **9**

- Wrong Site 3
- Wrong Patient 1
- Decay correction 1
- Right patient wrong treatment plan 1
- Source Retraction 1
- Wrong dwell time 1
- Wrong interpretation of dose per fraction 1

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35.600 Medical Events

HDR Wrong Site 3

- **OBGYN** - wrong location during three treatment fractions of 700 cGy (rad) per fraction
- During follow-up visit burns observed to the skin on the patient's thighs and labia.
- The estimated skin dose received by the patient was 4,200 cGy (rad).
- the source was 100 mm short of the intended treatment site due to Source reference length error,.

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35.600 Medical Events

HDR Wrong Site cont.

- **Broncial/tracheal -** each fraction had two segments, a distal portion using a simple catheter and a proximal portion using a centering catheter.
- In 1st fraction the centering catheter was positioned incorrectly
- Treatment offset of 9 cm superior to the intended treatment site

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35.600 Medical Events

HDR Wrong Site cont.

- **OBGYN** - first of three fractions vaginal cylinder position checked with planar digital x-ray image and unusual inferior cylinder placement was noted, attributed to special patient anatomy.
- On next fraction vaginal cylinder was approximately 5 cm superior to the first treatment..
- dose in 1st fraction to unintended tissue was 900 cGy (rad) and 100 cGy (rad) was to the intended tissue.

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35.600 Medical Events

HDR Wrong Patient – Skin 1

- physicist selected a different patient's treatment plan with shorter channel length
- The correct site and applicator were used
- Recognized error when time was too long – manually stopped procedure
- Intended treatment site received less than half of the 500 cGy (rad) intended dose,
- Area adjacent to the intended site received a maximum dose of 2,300 cGy (rad) to a single point and 1,000 cGy (rad) to a 1 cm radius and 4.5 mm depth

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35.600 Medical Events

HDR Decay correction – Skin 1

- Decay corrected value for the source activity was used in data entry for the treatment plan.
- HDR software also corrected for decay in determining the exposure time for the fraction
- patient received approximately twice the prescribed 600 cGy (rad) during a skin treatment

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35.600 Medical Events

HDR Wrong Treatment Plan – 1

- Two Ir-192 high dose rate (HDR) fractions of 700 cGy (rad) each
- The patient returned for the second fraction and treatment plan for the first fraction instead of the second fraction was loaded.
- 700 cGy (rad) to 60% of intended dose received by planned volume.

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35.600 Medical Events

HDR Source retraction – Pelvic 1

- Received 5.94 cGy (rad) of the prescribed 300 cGy (rad),
- First fractions, unexpected resistance detected in moved to the second dwell position.
- HDR unit detected a delay and automatically retracted the source.
- The dummy source wire could not traverse the pathway and the treatment was abandoned.

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35.600 Medical Events

HDR Dwell time – unspecified 1

- Before third of six fractions an error was identified in planning the correct dwell position for the first two fractions.
- Corrective actions included updating procedures to provide all catheter measurements, producing a checklist of necessary equipment for the operating room, briefing staff physicists in utilizing the equipment, and hiring additional staff.

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35.600 Medical Events

HDR Wrong interpretation of dose per fraction – OBGYN **1**

- Intended treatment was three fractions of 500 cGy (rad) each
- During the second of three fractions error noted
- Treatment plan was set to deliver three fractions for a total of 500 cGy (rad)
- Cause was attributed to human error.

35.600 Medical Events

Gamma knife 1

- Two similar patients arrived and had head frames attached
- Scheduling change to treat only patient 2 was made with out communicating the change to nursing staff
- Patient identification was not checked
- Physician realized mistake 2 minutes into the treatment
- 175 cGy (rad) to the wrong site.

Medical Events 2014

35.1000 Medical events **28**

Perfexion	**1**
I-125 Seed localization	**1**
Y-90 Microspheres	**24**
SirSphere®	15
Therasphere®	9
Gliasite	**1**

35.1000 Medical Events

Perfexion 1

- Treatment prescribed for left side of brain.
- Treatment planner set up plan for right side of brain as done for two previous treatments
- Incorrect treatment plan was reviewed and signed
- The treatment stopped at 1.72 minutes into the 19.14 minute procedure.
- Approximately 1,800 cGy (rad) deliver to wrong site.

35.1000 Medical Events

I-125 Seed localization 1

- received two I-125 seeds when only one was intended.
- The patient had two marker clips, one for benign biopsy site and other for a papilloma.
- the benign site was marked with a 9.32 MBq (252 µCi) I-125 seed
- The unintended dose from two days seed placement was 61 cGy (rad) at 0.5 cm

35.1000 Medical Events

Y-90 Microspheres **24**

SirSphere ® **15**

- Wrong site 2
- Written Directive 1
- 3-Way Stopcock 2
- Bubbles 1
- Contamination 1
- Transfer error 1
- Occluded /kinked catheters 6
- No Information 1

35.1000 Medical Events

SirSphere ® Wrong Site **2**

- **Duodenal Ulcer**
  - First of 3 treatments – 36.2 mCi (1,339 MBq)
  - Duodenum lesion and an ulcer that had developed seemingly as a result of microspheres migrating to the stomach.
  - A biopsy of the affected region revealed synthetic beads.
  - Aberrant hepatic arterial vasculature supplying the stomach.

35.1000 Medical Events

SirSphere ® Wrong Site cont.

- **Gastric fundus**
  - 1,100 cGy (rad) to the gastric fundus
  - Prescribed microspheres to the right liver lobe
  - Stopped when unanticipated shunting was identified.

35.1000 Medical Events

SirSphere® Written Directive 1

- **Over dose 36,300 rad instead of 10,200 rad**
  - Authorized user provided radiopharmacist with an incorrect version of the written directive treatment form
  - failure to follow all procedures and the defeat of normal checks and balances that should have identified the incorrect dosage

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35.1000 Medical Events

SirSphere® 3 Way Stopcock 2

- **45.8 % under Dose**
  - Majority of undelivered Y-90 in and around the 3-way stop
  - 3-way stop system was defective
- **29.7% under dose**
  - Microspheres in the tubing near the stop cock valve
  - Dextrose not Saline

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35.1000 Medical Events

SirSphere®

- **75 % under Dose**
  - Noticed bubbles in the administration line during the treatment and stopped.
- **44.7 % under dose**
  - elevated readings at the catheter/vial interface - coagulation of microspheres.
  - contamination on physician's glove and table

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35.1000 Medical Events

SirSphere®

- **34 % under Dose**
  - Error transferring microspheres from the delivery vial to the dosing via.
- **22.7 % under dose**
  - Larger than expected amount of microspheres remained in the needle and tubing and did not reach the patient.

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35.1000 Medical Events

SirSphere ®

- **22.5 and 30 % under Dose**
  - Split dose, not detected until end of both.
  - Blockage in the delivery system.
- **25 % under dose**
  - catheter clogged halfway through the procedure
  - catheter removed, replaced, and remaining microspheres administered

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35.1000 Medical Events

SirSphere ®

- **41% under Dose**
  - Same lobe but two different arterial pathways.
  - No microspheres delivered to second part.
  - Short arterial segment and the acute angle at the arterial origin, with possible manipulation or patient movement, resulted in a kink or fold

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35.1000 Medical Events

SirSphere ®

- **41.1% under Dose**
  - blockage
  - Not problem with administration kit .
  - Significant number of kinks, bends, clots, and other blockages at catheter tip
- **32.2 under Dose**
  - last bolus could not be pushed through

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35.1000 Medical Events

SirSphere ®

- **38% under Dose**
  - No information provided

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35.1000 Medical Events

Y-90 Microspheres cont.

Therasphere ®	9
– Wrong site	2
– Reflux & Precipitated out	1
– Dosage error	1
– Remained in vial	1
– Settle out /kink	4

35.1000 Medical Events

Therasphere® Wrong Site 2

- **SHUNTING** - Two tumors right and left lobes
  - – Tested right hepatic artery found shunting - intended 370 cGy (rad) to lung
  - – Treated left lobe through left hepatic artery – untested shunting
  - – lungs received 3,450 cGy (rad)
  - – Patient died 5 months later

35.1000 Medical Events

Therasphere®

Wrong site - Catheter Position Error

- Could not properly position the catheter for Segment IV
- Bilateral disease that would eventually require the treatment of both lobes
- 0.81 GBq (21.8 mCi) to Segment IV and 0.91 GBq (24.5 mCi) in the right lobe.

35.1000 Medical Events

Therasphere®

Reflux & Precipitated out

- 24 % under dose – noted some reflux into the common hepatic artery/gastroduodenal artery.
- reduced flow rate during administration process, which resulted in the precipitation of microspheres along the outflow tube

35.1000 Medical Events

Therasphere®

Dosage error over dose

- Written directive for 20 % less activity.
- Reviewed treatment plan but verified standard activity not prescribed activity

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35.1000 Medical Events

Therasphere®

- **20% remained in vial**
- **44% under dose**
  - Targeting vessel was flowing slowly
  - Microspheres to settle out prior to reaching the target.
- **73 % under dose**
  - Wrong catheter - kinking

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35.1000 Medical Events

Therasphere®

- **23.5% under dose**
  - Microspheres adhered to the connector and first one inch of manufacturer supplied tubing
- **28.7% under dose**
  - kink in the delivery catheter - created blockage
  - thinner, more flexible catheter walls and a small internal catheter diameter were contributing factors.

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35.1000 Medical Events

GliaSite

- **No dose to treatment site**
  - The balloon had not inflated incorrectly positioning a three-position stopcock
  - I-125 saline solution being diverted to another syringe instead of filling the balloon.
  - The stopcock was not part of the vendor's kit

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Acronyms

- FY – Fiscal Year
- HDR – High Dose Rate Remote Afterloader
- mCi – millicurie
- MBq – Mega Becquerel
- Pts - Patients
- Y – Yttrium
- I-131 – Iodine-131

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QUESTIONS?

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