



Status of Medical Events FY 2014

Donna-Beth Howe, Ph.D.
 Medical Radiation Safety Team
 March 19, 2015



Medical Events 2014

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

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



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 2014

35.200 Medical events **1**

Technetium-99m

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



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

5



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

6



Medical Events 2014

35.400 Medical events **5**

Gynecological 1

Prostate 4

7



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).

8



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

9



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

10



Medical Events 2014

35.600 Medical events

10

HDR

9

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

11



Medical Events 2013

35.600 Medical events

9

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

12

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,.

13

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

14

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.

15

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

16

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

17

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.

18

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.

19

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.

20

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.

21

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.

22

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

23

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.

24

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

25

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

26

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.

27

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.

28

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

29

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 stopcock valve
 - Dextrose not Saline

30

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

31

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.

32

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

33

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

34

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

35

35.1000 Medical Events

SirSphere®

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

36

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

41

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

42

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.

43

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

44

Acronyms

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

45

QUESTIONS?

46