Status of Medical Events FY 2016

Donna-Beth Howe, Ph.D.
Medical Radiation Safety Team
April 26, 2017

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**

	FY11	FY12	FY 13
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**

	FY14	FY15	FY16
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

4

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.

9

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.

10

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 tandum 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.

14

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.

15

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.

21

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).

22

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

Perfexion 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.

25

35.600 Medical Events

Perfexion cont.

- **Estimated Administerion 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

Perfexion 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.

27

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..

28

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.

31

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.

32

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.

33

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.

34

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.

35

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.

36

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.

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.

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.

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.

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).**

41

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

42

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 doseage 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.

43

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.

44

35.1000 Y-90 Events (cont.)

SirSphere ® aparatus 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.

45

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.

46

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.

47

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.

48

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.

49

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.

50

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.

51

35.1000 Y-90 Events

SirSphere ® no description/reason

Administered 79.5% of their prescribed dose.

- 20.5% of dose found in device/waste.

52

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
- µCi – microcurie
- MBq – Mega Becquerel

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

QUESTIONS?

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

Other Medical Byproduct Material Events FY 16

Susan M. Langhorst, Ph.D., CHP
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**

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

Categories

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

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]**

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

8

Acronyms

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

9