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

Medical Events Report FY 2016 Reported 10/1/15 - 9/30/16

Ronald D. Ennis, M.D.

Advisory Committee for the Medical Uses of Isotopes

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U.S.NRC Subcommittee Members

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U.S.NRC 35.200 Use of Unsealed Byproduct Material for Imaging and Localization

8 events: 7 ^{99m}Tc & 1 ^{18}F-FDG

1. Entire 4.74 GBq (128 mCi) multidose vial of ^{99m}Tc-diphosphonate administered to one patient

   8 cGy whole body

   Cause

   Staff member did not confirm amount of activity to be administered

   Corrective action

   Licensee will no longer prepare kits

U.S.NRC 35.200 Use of Unsealed Byproduct Material for Imaging and Localization

2. Intravenous port leak

   Skin exposure exceeded 50 (cSv)(rem)

3. 88 MBq (2.4 mCi) unfiltered ^{99m}Tc-sulfur colloid, intended for gastric emptying study, administered for lymphoscintigraphy, instead of prescribed 18.5 – 37 MBq (500 uCi-1 mCi) filtered ^{99m}Tc-sulfur colloid

   Potential 58.08 - 273.6 cSv (rem) to skin

Corrective action

Technologist must verbally confirm activity and procedure with physician prior to administration

35.200 Use of Unsealed Byproduct Material for Imaging and Localization

4. 1.11 GBq (30 mCi) ^{99m}Tc-diphosphonate, instead of 18.5 MBq (500 uCi) ^{99m}Tc administered for sentinel node procedure

   Cause

   Miscommunication

   Technologist failed to confirm patient identity with procedure

35.200 Use of Unsealed Byproduct Material for Imaging and Localization

5. 373 MBq (10.1 mCi) Tc-99m tetrofosmin administered to wrong patient

   Cause

   Not specified

   Corrective action

   Being developed

35.200 Use of Unsealed Byproduct Material for Imaging and Localization

6. 925 MBq (25 mCi) ^{99m}Tc-diphosphonate, instead of 18.5 MBq (500 uCi) ^{99m}Tc-sulfur colloid administered for gastric emptying procedure (retracted 8/2/2016, CFR dose limits not exceeded)

35.200 Use of Unsealed Byproduct Material for Imaging and Localization

7. 199.8 MBq (5.4 mCi) 99m-Tc-hepatobiliary agent, instead of 18.5 MBq (500 uCi) Tc administered for gastric emptying

   Cause

   Human error

   Corrective action

   Order capture procedure changed and technologists retrained

35.200 Use of Unsealed Byproduct Material for Imaging and Localization

8. 603.1 MBq (16.3 mCi) ^{18}F-FDG administered to wrong patient

   Cause

   Human error: Two patients with same last name

   Order & supporting documentation confusing

   Corrective action

   Technologist review with supervisor

   Workflow sheet revision

35.300 Use of Unsealed Byproduct Material, Written Directive Required

5 events

Radium-223:	**3**
Samarium-153:	**1**
Iodine-131:	**1**

35.300 Use of Unsealed Byproduct Material, Written Directive Required

^{223}Ra

1. Pt. received 4.41 MBq (119.3 uCi) Ra-223 instead of prescribed 3.21 MBq (86.7 uCi)

   Cause

   Technologist failed to confirm patient's identity and weight prior to radiopharmaceutical administration

   Corrective action

   Institution of additional administrative actions

35.300 Use of Unsealed Byproduct Material, Written Directive Required

2. Pt. received 3.7 MBq (99.4.µCi) instead of prescribed 36.3 MBq (980 µCi)

   Cause

   Failure to observe discrepancy between prescribed and calibrated activity

   Licensee believed AU intended to prescribe 98 µCi (more typical dosage)

   Corrective action

   Activity will be listed in microcuries instead of millicuries

   N.B. Licensee correct

35.300 Use of Unsealed Byproduct Material, Written Directive Required

3. Pt. received Ra-223 at a clinic that is not an authorized use location for this material. Not administered by an AU

   Clinic may, prior to merger, have been Authorized Use Location and MD previously may have been AU.

   AU review indicated that amount of activity prescribed was appropriate

   Corrective action

   All future treatments will be administered at an authorized facility with an AU

35.300 Use of Unsealed Byproduct Material, Written Directive Required

^{153}Sm

1. Patient received 3.22 GBq (86.9 mCi) instead of 2.48 GBq (67.13 mCi).

   Cause

   Dosage from pharmacy was not correctly calculated for patient weight

35.300 Use of Unsealed Byproduct Material, Written Directive Required

^{131}I

1. Pt. received 1.96 GBq (53 mCi) instead of 4.47 GBq (120.8 mCi)

   Cause

   Total activity delivered in two capsules, but only one capsule administered

   Corrective action

   Licensee to revise procedures for transfer of radioactive materials

35.400 Non-Prostate Manual Brachytherapy

Cervix Cs-137

Sources: 44.46 mCi, 33.73 mCi, 25.39 mCi, 25.39 mCi. (Unspecified which sources in tandem)

- Catheter containing sources for tandem placed in wrong well for transport to patient room
- End of catheter crushed by cover of transport shield
- Unable to insert fully into tandem
- Catheter cut off to enable fit
- Result in sources not fully inserted

35.400 Non-Prostate Manual Brachytherapy

Cervix Cs-137 cont.

Underdose of tumor 1500 cGy instead of 3460 cGy

Overdose to lower rectum and vagina of 3492 cGy

Cause – inadequate training and written procedures contributed to human error

Corrective action – revising procedures, training personnel, improved supervision

35.400 Prostate Manual Brachytherapy

- 1 hospital with 2 events with Pd-103. D90 67% and 71% of prescribed 12,500 cGy. Unclear if would be ME based on new ME definition. No additional information such as root cause analysis provided.
- This led to retrospective investigation and an additional 13 events found. No details provided re: these.

35.400 Prostate Manual Brachytherapy

- I-125. D90 70%. But, 92% of activity was implanted in prostate (16.039 mCi out of planned 17.404 mCi). So, would not have been ME based on new definition. AU gave additional external radiation. Cause attributed to human error
- I-125: D90 60%, based on activity 58% implanted in prostate. Found by hospital in 2014. Discovered by regulator on inspection in 2015. Cause: Human error. Corrective action: Procedure modification and new training

35.400 Prostate Manual Brachytherapy

- I-125: D90 67%. No comment on activity. Cause seed migration. Corrective action: New training, new technique
- 1-125: Implanted a mass mistakenly thought to be prostate due to abnormal anatomy. Corrective action: New quality management plan, new written procedures and training.

35.600 HDR Brachytherapy

Event Site	Number of Events
Prostate	2
Gynecological	2
Skin	1

35.600 HDR Brachytherapy

- 1 wrong positioning of catheter
  - Thigh (instead of vagina) treated with 1000 cGy inadvertently, resulting in skin wound. Modified procedures.
- 1 wrong patient's plan delivered
  - Instituted time out policy.

35.600 HDR Brachytherapy

- 3 Equipment failures
  - 3 partial treatments. All worked with manufacturer and fixed or no problem found. Seems that treatment was eventually completed for two patient. No information about what was done as a consequence of the event for the other. (Delivered 103 cGy of planned 600 cGy for that treatment.)

35.1000 Perfexion

Gamma Knife Perfexion – 3 events

1. Treatment of right rather than left trigeminal nerve.
2. Treatment stopped to sedate patient. After 2 mins of restarting treatment, patient moved significantly. Frame was not in position at end of treatment. Timing of frame being dislodged is uncertain (not reportable).
3. Frame adapter was in the wrong position. Displaced distance was 2 cm in the direction of one plane. Error was attributed to using a new adapter without having received proper training from the manufacturer.

35.1000 Perfexion

Corrective Actions

- Procedure modification for incorrect treatment site.
- Proper training when using new frame adapters

35.1000 Y-90 Microspheres

	FY2013	FY2014	FY2015	FY2016
All ^{90}Y Microspheres	13	23	14	19
SIR-Spheres*	10	16	6	7
TheraSpheres	3	7	8	12

* ~8,400 doses sold in US in calendar year 2016

35.1000 Y-90 Microspheres Brachytherapy

16 / 19 – Wrong dose: 3-80% (14), 119-129% (2*)

- 5 – Obstruction in tubing
- 1 – Human error: Unspecified
- 1 – Human error: Residual activity incorrectly assayed
- 1 – Human error: Liver volume incorrectly calculated*
- 1 – Human error: Activity incorrectly calculated*
- 1 – Human error: Excessive activity left in vial
- 1 – Leak through needle hole in vial septum
- 1 – Breach of procedure: 3-way stopcock in circuit
- 4 – Cause not specified (possibly stasis?)

35.1000 Y-90 Microspheres Brachytherapy

4 /19 – Wrong site (incorrect liver segment)

2 /4 – "Catheter tip moved"

1 / 19 – Wrong patient / Wrong dose/ Wrong site

- For under-doses where administered activity <75% of prescribed activity: Patients generally re-treated
- For over-dose: No clinically demonstrable liver toxicity

35.1000 Radioactive Seed Localization

2 / 2 – Radioactive seeds not removed as scheduled due to deterioration of patient condition and risk of surgery

1 – Seeds removed 2 months later; 297 cGy to 1 cm, 40 cGy dose to breast

1 – Seeds not removed as of last report (3 month post-implantation); 73 cGy dose to breast

Patient intervention, not MEs?

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Summary of MEs FY13-FY16

	FY 2013	FY 2014	FY 2015	FY 2016
35.200	2	6	4	8
35.300	2	4	7	5
Manual brachy	16	5	8	7
HDR	8	9	13	5
GK	2	2	1	3
Microspheres	13	23	14	19
RSL	1	2	0	2

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Conclusions

- No obvious trends or patterns but there are two lead causes:
  - Errors that could be detected by a "time out" prior to treatment/procedure (N=~9)
  - Microspheres
- Each year there are ~15M diagnostic and 150K therapeutic procedures performed utilizing radioactive materials
- The tiny fraction presented here today is reassuring and confirms the generally safe fashion these materials are administered to patients in the USA

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Acronyms

- cm – centimeter
- Cs – Cesium
- FY – Fiscal Year
- Gy – Gray
- HDR – High dose-rate
- I – Iodine
- MBq – megabequerel
- mCi – millicurie
- ME – Medical Event
- Pd – Palladium
- Pt(s) – Patient(s)
- QA - Quality Assurance
- rem – roentgen equivalent in man
- Y- Yttrium

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