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

Medical Events Report FY 2015

Ronald D. Ennis, M.D.

Advisory Committee for the Medical Uses of Isotopes

October, 2016

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

Subcommittee members

- Ronald D. Ennis, M.D. (Chair)
- Susan Langhorst, Ph.D.
- Michael O'Hara, Ph.D.
- Christopher Palestro, M.D.
- John Suh, M.D.
- Pat Zanzonico, Ph.D.

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

35.200 Use of Unsealed Byproduct Material for Imaging and Localization

- Time Period:10/1/2014 - 9/30/2015
- 4 events
  - ^{99m}Tc: 3 events
    - Myocardial perfusion studies:2
    - Lymphoscintigraphy: 1
  - ^{123}I: 1 event
    - Thyroid

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

35.200 Use of Unsealed Byproduct Material for Imaging and Localization

- ^{99m}Tc

  Myocardial perfusion studies

  (1) 4.37 GBq (118 mCi) $^{99m}TcO_4^-$ administered instead of 480 MBq (12.9 mCi) ^{99m}Tc-sestamibi. Failure to follow proper procedures

  (2) 5.92 GBq (160 mCi) $^{99m}TcO_4^-$ administered instead of 1.11 GBq (30 mCi) ^{99m}Tc-tetrofosmin. Caused by inattention to detail.

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

35.200 Use of Unsealed Byproduct Material for Imaging and Localization

- ^{99m}Tc

  Lymphoscintigraphy
  Patient received 1.11 GBq (30 mCi) ^{99m}Tc-MDP instead of 18.5 MBq ^{99m}Tc for sentinel node procedure. Technologist failed to verify patient ID on doseage pig prior to administration.

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

35.200 Use of Unsealed Byproduct Material for Imaging and Localization

- ^{123}I

  Thyroid
  136.53 MBq (3.69 mCi) ^{123}I (NaI) administered instead of 11.1 MBq (300 uCi) ^{123}I (NaI). Caused by human error

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

35.300 Use of Unsealed Byproduct Material, Written Directive Required

- Time Period:10/1/2014 - 9/30/2015
- 7 events
  - ^{131}I: 5
  - $^{223}RCl_2$: 1
  - ^{124}I-H89: 1

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

35.300 Use of Unsealed Byproduct Material, Written Directive Required

- ^{131}I

  (1) Pt. received 1.85 GBq (50 mCi) instead of 1.30 GBq (35 mCi) (42.8% overdose). Technologist failed to confirm activity and selected wrong doseage.

  (2) Pt. received 1.14 GBq (30.8.mCi) instead of 111 MBq (3 mCi) (927% overdose). Intended prescription was 1.18 GBq (32 mCi) Written directive incorrectly annotated

35.300 Use of Unsealed Byproduct Material, Written Directive Required

- ^{131}I

(3) Pt. received 5.3 GBq (143.2 mCi) instead of 1.11 GBq (30 mCi) (377% overdose). Technologist selected wrong vial & didn't confirm written directive.

(4) Pt. received 2.775 GBq (75 mCi) instead of 5.55 GBq (150 mCi) (50% underdose). Dosage supplied in 2 capsules, but only one was administered.

9

35.300 Use of Unsealed Byproduct Material, Written Directive Required

- ^{131}I

(5) Pt. received 58.09 MBq (1.57 mCi) instead of 74 MBq (2.0 mCi) (21.5% underdose). Caused by failure to follow procedures.

10

35.300 Use of Unsealed Byproduct Material, Written Directive Required

- ^{223}Ra

Pt. received 7.65 MBq (206.8.uCi) instead of 4 MBq (108 uCi) (91.48% overdose). Technologist misread prescribed dose and administered both doseages.

11

35.300 Use of Unsealed Byproduct Material, Written Directive Required

^{124}I-8H9 (monoclonal Ab)

Pt.received 64.38 MBq (1.74 mCi) instead of prescribed 120.25 MBq (3.25 mCi) (53% underdose) because of leakage at catheter connector site not obvious on visual inspection

12

35.400 Medical Events 2013-2015

35.400 Medical events	2013: 16 MEs (18 patients)	2014: 5 ME's	2015
Gynecological	2	1	0
Prostate	14 (16 patients)	4	7 (8 patients)
Head and Neck	0	0	1

35.400 Medical Events Non-Prostate Manual Brachytherapy

Head and Neck - Tongue Ir-192

- 5 strands of Ir-192 implanted.
- One strand missing when MD checked at Noon. Had been in place in AM. Found in linen which had been changed at 10AM.
- Reinserted and treatment completed.
- Not reported initially
- On site visit – possible unintended skin dose of 51.75 rem – ME
- No patient toxicity
- Cause "procedure" problem
- Corrective action – "wrote new policy"

35.400 Medical Events Prostate Manual Brachytherapy

- 7 Medical Events (8 Patients)
- Physicians mistook penile bulb as prostate
  - Licensee determined the US unit had been serviced by vendor prior the procedure. Some calibration settings were changed (i.e. gain). This led to the error in identifying correct structure.
  - No attribution to MD error
  - Corrective action – Implemented procedures to assure efficacy of US after service prior to use

35.400 Medical Events Prostate Manual Brachytherapy

- Patient received 28% more dose than intended
  - Ordered seeds based on air kerma instead of mCi. Also ordered 4 more seeds than prescribed.
  - Corrective action – new procedures, improve material labeling, handling protocols and new training
- Patient received 49% more dose than intended
  - Prescribed 13.4 mCi to deliver 10,700 cGy (boost treatment) but delivered 18.3 mCi to deliver 16,000 as full treatment
  - Corrective action modified procedures to confirm and document the implant dose.
  - Did not proceed with the planned external beam treatment

35.400 Medical Events Prostate Manual Brachytherapy

- Patient received 27% less the prescribed
  - Detected on investigation
  - No other details provided
  - Licensee sited for failure to develop written procedures, failure to perform acceptance testing of computer systems, failure to properly document post-procedure written directives, failure to conduct adequate annual review of radiation safety program
  - Licensee requested to hire medical physicist to audit safety program and recommend corrections

17

35.400 Medical Events Prostate Manual Brachytherapy

- Investigation because of "irregularities" found in a licensee's practice and therefore retrospectively reviewed prior cases
  - This may be related to prior case – different site of same corporate entity
  - Found 2 MEs of lower dose than prescribed – 37% of prescribed and 67% of prescribed. Both Pd-103.
  - No further information provided

18

35.400 Medical Events Prostate Manual Brachytherapy

- D90 34% less the prescribed dose
  - Later retracted due to further investigation by regulator
- Misplacement of seeds resulting in higher dose to rectum by 61%.
  - No cause other than "inherent difficulty in the procedure"

19

35.600 Remote Afterloaders, Teletherapy, Gamma Knife

	FY2013	FY2014	FY2015
All § 35.600	9	10	13
All HDR	8	9	13
LDR remote afterloader	0	0	0
Gamma Knife	1 (+1 Perfexion)	1 (+1 Perfexion)	(+1 Perfexion)
Teletherapy	0	0	0

HDR Brachytherapy Sites

Event Site	Number of Events
Breast	1
Gynecological (mostly vaginal cylinders)	9
Skin	1
Bronchus	2

35.600 HDR Brachytherapy Observations

- 8 Positioning problems:
  - 5 Wrong positioning,
  - 3 Wrong reference length entered,
- 2 Wrong patient's plan delivered
- 1 Deficient treatment plan
- 2 Machine problems

35.600 HDR Brachytherapy Observations

- Action plans
  - Personnel training, especially when upgrading or changing treatment units
  - Proper timeouts
  - Verification of cylinder placement before, during and after treatment
  - Manufacturer notification

35.600/35.1000 GammaKnife Medical Events

- Gamma Knife - 0 event (§ 35.600)
- Gamma Knife Perfexion – 1 event (§ 35.1000)
  - Misalignment of the patient positioning system for 8 patients. Off-target by 1.87 mm. Dose exceeded prescribed dose by 100%.
  - Action plan
    - Development of new set of tests to verify patient positioning

§ 35.1000 Medical Events

	FY2013	FY2014	FY2015
All § 35.1000	15	26	14 18 patients
All Microsphere	13	23	14 18 pts.
SIR-Spheres	10	16	6
TheraSphere	3	7	8/12
Radioactive Seed Localization	1	2	0

§ 35.1000 Medical Events Microspheres

3 - retained microspheres in catheter/tubing, hub, vial (3 Therasphere, 1 SIR) (78%, 58% and 67% of prescribed dose delivered)

5 – use of small catheters which led to microspheres retained in hub (1 institution, Therasphere) (all <80%, NOS)

1 - incorrect set-up of tubing (SIR) (79%)

1 - incorrect tightening of tubing connection leading to leak (SIR) (42%)

1 - kink in tubing (Therasphere) (35%)

§ 35.1000 Medical Events Microspheres

1 - low flow due to small arteries. 77% of dose delivered.

1 - Stomach received 57.5 rem. Detected on post-treatment scan. Infusion had been discontinued after 64% due to stasis.

1 - catheter moved, perhaps when fluoro table was moved, and infused 38% to superior mesenteric artery to small bowel. Did not re-image after moved table. Corrective action procedure modifications and additional training. Led to hospitalization of patient for pain. (SIR)

§ 35.1000 Medical Events Microspheres

2 wrong artery

1 – wrong hepatic artery, treated left lobe (segment 4) instead of right lobe (segments 1,5,6,7,8). Corrective action – have angiogram present at procedure

1 – renal artery instead of hepatic artery.

High dose (1345 Gy) to kidney. First procedure done by licensee. No kidney damage observed (yet). Corrective action – formal checklist, mapping images at procedure, review of position by second MD

28

§ 35.1000 Medical Events Microspheres

- 2 – reported underdose that were later retracted when further investigation revealed correct dose given

29

Other Medical Byproduct Material Events

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

30

Other Medical Byproduct Material Events – identified in FY15 [FY14]

Categories

- Miscellaneous – 12 [8]
- Leaking sealed sources – 4 [4]
- Lost materials/sources (no Cat. 1 or 2) – 24 [30]
- Shipping issues – 12 [10]
- Landfill alarms – 114 [113]

31

Other Events – Miscellaneous FY15 [FY14]

- Occupational overexposure – 6 [2]
- Suspected public overexposure – 0 [1]
- Airborne constraint exceeded – 0 [1]
- Equipment failures – 3 [3]
- Contamination – 2 [0]
- Recordkeeping – 1 [0]
- Suspicious activity – 0 [1]

32

Other Events – Leaking sealed sources FY15 [FY14]

- Cs-137 source (<300 µCi) – 0 [2]
- Co-57 line source – 0 [1]
- I-125 source (localization) – 2 [1]
- I-125 source (eye plaque) – 1 [0]
- Pd-103 source (prostate seed) – 1 [0]

33

Other Events – Lost materials/sources FY15 [FY14]

- Lost after procedure (I-125) – 10 [10]
- Lost/found/lost and found – 4/1/0 [2/2/4]
- Lost during shipment – 8 [6]
- Package thrown away – 0 [1]
- Licensee out of business – 0 [1]
- Theft – 0 [3]
- Buried pacemaker – 1 [0]

34

Other Events – Shipping issues FY15 [FY14]

- Delivered wrong address/location – 4 [5]
- Stored in unsecured area – 1 [1]
- Accident/Highway Patrol delivery – 0 [1]
- Shipping package issues – 7 [2]
- No license approval for receipt – 0 [1]

35

Other Events – Landfill

Isotope	Hospital	Residence	Not identified
I-131	6 [2]	10 [23]	58 [37]
In-111	1 [1]	2 [0]	1 [2]
Tc-99m	3 [18]		10 [14]
Tl-201	0 [3]	1 [0]	1 [0]
Not identified	0 [3]	0 [3]	21 [7]

Reports from Agreement States –

18 [12]% AL 81 [85]% CA 1 [1]% FL 0 [1]% NC 1 [2]% DC

36

Conclusions

- No obvious trends or patterns this year
- Each year there are ~15,000,000 diagnostic and 150,000 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

Acronyms

- cm – centimeter
- Cs – Cesium
- FY – Fiscal Year
- Gy (rad) – Gray
- GYN – gynecological
- HDR – High dose-rate
- I – Iodine
- LDR – Low dose-rate
- MBq – megabequerel

Acronyms

- mCi – millicurie
- ME – Medical Event
- NMED – Nuclear Material Events Database
- Pd – Palladium
- Pt(s) – Patient(s)
- QA – Quality Assurance
- rem – roentgen equivalent in man
- Y – Yttrium