



Medical Events Report FY 2015

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Advisory Committee for the
Medical Uses of Isotopes
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Subcommittee members

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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



35.200 Use of Unsealed Byproduct Material for Imaging and Localization

- ^{99m}Tc
 - Myocardial perfusion studies
 - (1) 4.37 GBq (118 mCi) $^{99m}\text{TcO}_4^-$ administered instead of 480 MBq (12.9 mCi) ^{99m}Tc -sestamibi. Failure to follow proper procedures
 - (2) 5.92 GBq (160 mCi) $^{99m}\text{TcO}_4^-$ administered instead of 1.11 GBq (30 mCi) ^{99m}Tc -tetrofosmin. Caused by inattention to detail.

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.

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35.200 Use of Unsealed Byproduct Material for Imaging and Localization

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

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35.300 Use of Unsealed Byproduct Material, Written Directive Required

- Time Period:10/1/2014 - 9/30/2015
- 7 events
 - ¹³¹I: 5
 - ²²³RCl₂: 1
 - ¹²⁴I-H89: 1

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35.300 Use of Unsealed Byproduct Material, Written Directive Required

- ¹³¹I
 - (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

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**35.300 Use of Unsealed Byproduct Material,
Written Directive Required**

- ¹³¹I
(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). Doseage supplied in 2 capsules, but only one was administered.

**35.300 Use of Unsealed Byproduct Material,
Written Directive Required**

- ¹³¹I
(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.

**35.300 Use of Unsealed Byproduct Material,
Written Directive Required**

- ²²³Ra
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.

**35.300 Use of Unsealed Byproduct Material,
Written Directive Required**

- ¹²⁴I-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

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

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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"

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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

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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

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**35.400 Medical Events
Prostate Manual Brachytherapy**

- Patient received 27% less the prescribed
 - Detected on investigation
 - No other details provided
 - Licensee cited 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

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**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

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**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”

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**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)	1 (+1)	(+1)
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



§ 35.1000 Medical Events Microspheres

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

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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

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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]

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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]

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**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]

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**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]

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**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]

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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

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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

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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

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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

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