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

Medical Events Report FY 2014

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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

- Date Reported: >= 10/1/2013 and <= 9/30/2014
- 6 events
- In FY2014 were 2 events
- In 5 of the events the technologist
  - failed to calibrate the dose and/or,
  - failed to selected the correct dose, even though the radiopharmaceutical was properly labeled

35.200 Use of unsealed byproduct material for imaging and localization

- NMED 140019: 18.5 MBq (500 mCi) In-111 Leukocyte (WBC) dose injected to wrong patient
- Technologist failed to identify correct patient.
- Biggest concern is potential biologic effect, not the unintended radiation exposure
- In essence an unplanned blood transfusion
  - from a ill patient vs. a healthy donor
  - leukocytes (WBC) transfusion may have an incompatible blood type and/or pathogens or viruses

35.300 Use of unsealed byproduct material, Written Directive Required

- Date Reported: >= 10/1/2013 and <= 9/30/2014
- 4 events
- In FY2013 there were 2 events
- 1 event; the technologist selected the wrong I-131 dose, selected an expired and now a non-radioactive dose (?) vs. the correct dose

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35.300 Use of unsealed byproduct material, Written Directive Required

- 1 event; 39 mCi of the Sm-153 dose was extravasated during administration, of the intended 100 mCi dose
- 1 event; patient received 1 of 2 capsules for 150 mCi dose of I-131
- Both events, not enough information to assess

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35.300 Use of unsealed byproduct material, Written Directive Required

- NMED 140069 1.11 MBq (30 mCi) I-131 dose to the wrong patient
- Patient did not speak English
- Registrar attached wrong wrist ID band
- Physician failed to correctly identify the patient
- Misadministration was noticed before patient left the hospital, administered a thyroid blocking agent.

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Manual Implant Brachytherapy

- Event Type = Medical; Date Reported to NRC >= 10/1/2013 and <= 9/30/2014; Medical Event: Procedure Given = BRACHY, MANUAL IMPLANT and BRACHY, MANUAL AFTERLOADER
- 30 events total
- But since 23 Y-90 microspheres and 2 breast localizations are § 35.1000, only 5 § 35.400 events: 4 prostate, 1 gynecological

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Medical Events 2013

35.400 Medical events	2013: 16 MEs (18 patients)	2014: 5 ME's
Gynecological	2	1
Prostate	14 (16 patients)	4

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35.400 Medical Events Non-Prostate Manual Brachytherapy

Gynecological Cs-137 1

- A) 15.09 Gy (rad) to skin of inner thigh – vaginal applicator was dislodged in patient who had partial paralysis below waist. Implant was in place at least 49.5 hours (54.91 Gy) of planned 63.1 hour (70 Gy) implant. Treatment site received 78% of intended dose.

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35.400 Medical Events Non-Prostate Manual Brachytherapy

- Patient had restless night and tossed and turned
- She did not recognize applicator was dislodged
- Daily skin checks in Dec 2013 showed no adverse effects
- Corrective action: more frequent checks of applicator position and providing new training to personnel

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35.400 Medical Events Prostate Manual Brachytherapy

- 4 Medical Events (4 Patients)
- Multiple Medical Events: 0
- 3 underdoses and 1 overdose
- 1 calculation plan error and 3 seed misplacement
- I-125: 4 pts; Pd-103: 0 pts; Cs-131: 0

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35.400 Medical Events

Prostate: 4

- Implant of scar tissue
  - Corrective action: procedure modification and training ultrasound
- Seeds placed 3.5 cm inferior. Foley balloon was pierced and deflated
  - Corrective action: training ultrasound
- Use of mCi rather than air kerma value (184 Gy rather than 145 Gy)
  - Corrective action: Physician checks calibration sheet and values
- Physicians mistook penile bulb as prostate
  - Corrective action: centralize seed program, follow policies, Q/A of ultrasound and training

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35.600 Remote Afterloaders, Teletherapy, Gamma Knife

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

HDR Brachytherapy Sites

Event Site	Number of Events
Breast	1
Gynecological (Vaginal cylinders – Although some not clear)	5
Skin	2
Bronchus	1

35.600 HDR Brachytherapy Observations

- 4 Positioning problems:
  - 2 Wrong positioning,
  - 2 Wrong reference length entered,
- 1 Wrong patient's plan
- 2 Wrong dose entered or wrong source strength entered
- 2 Machine problems

35.600/35.1000 GammaKnife Medical Events

- Gamma Knife - 1 event (§ 35.600)
  - Scheduling change lead to wrong patient's plan used and wrong side treated
- Gamma Knife Perfexion – 1 event (§ 35.1000)
  - Wrong site and wrong side due to poor communication with treatment planner

§ 35.1000 Events

	FY2013	FY2014
All § 35.1000	15*	26*
All Microsphere	13	23
SIR-Spheres	10	16
TheraSphere	3	7
Radioactive Seed Localization	1	2

*Includes the Perfexion event already considered

§ 35.1000 Events

16 SIR-Spheres Events
- 10 Catheter blocked/ material left in equipment
- 2 Dose calculation error
- 1 Error in drawing dose
- 2 Unexpected shunts
- 1 Unspecified

§ 35.1000 Events

7 TheraSpheres Events
- 1 Unexpected shunt
- 6 Catheter blocked/ material left in equipment

§ 35.1000 Events

2 Radioactive Seed Localization Events

- 1 seed fall during tumor removal, found and retrieved 49 days later
- 1 Two seeds used when only one was ordered on the written directive

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

Categories

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

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Other Events - Miscellaneous

- Occupational overexposure – 2
- Suspected public overexposure – 1
- Airborne constraint exceeded – 1
- Equipment failures – 3
- Suspicious activity – 1

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Other Events – Leaking Sealed Sources

- Cs-137 source (<300 µCi) – 2
- I-125 source (localization) – 1
- Co-57 line source – 1

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Other Events – Lost Materials/Sources

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

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Other Events – Shipping Issues

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

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Other Events - Landfill

Isotope	Hospital	Residence	Not identified
I-131	2	23	37
In-111	1		2
Tc-99m	18		14
Tl-201	3		
Not identified	3	3	7

Reports from Agreement States –

12% AL 85% CA 1% FL 1% NC 2% NC

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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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