

Medical Events Report FY 2015

Ronald D. Ennis, M.D. Advisory Committee for the Medical Uses of Isotopes October, 2016

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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
 - ¹²³I: 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}TcO₄- administered instead of 480 MBq (12.9 mCi) ^{99m}Tc-sestamibi. Failure to follow proper procedures
 (2) 5 92 GBn (160 mCi) ^{99m}TcO₄- administered instead

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



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.



35.200 Use of Unsealed Byproduct Material for Imaging and Localization

• 123

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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

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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

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(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

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(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.

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35.300 Use of Unsealed Byproduct Material, Written Directive Required

• ¹³¹

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(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.

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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.

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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

Usited States Nuclear Regulatory Co Protecting People and the Event	mmission	Medical Evo 015	ents
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
			13

WUSINEC Weight Strands Transformer Source Stars Strands of Ir-192 implanted. Source 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"

USNRC 35.400 Medical Events Verde Sear Note: Register, Committee 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



35.400 Medical Events Prostate Manual Brachytherapy

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- · 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



35.400 Medical Events Prostate Manual Brachytherapy

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- 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.
 - biescribed and or // or prescribed. Both
 - No further information provided

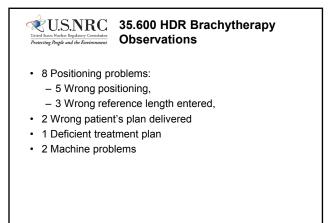
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35.400 Medical Events Prostate Manual Brachytherapy

- 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"

US.NRC United States Nuclear Regulatory Controlision Protecting People and the Exteriornment	35.600 Rem Teletherapy		•
	FY2013	FY2014	FY2015
All § 35.600	9	10	13
All HDR	8	9	13
LDR remote afterloader	0	0	0
	1 (+1	1 (+1	(+1
Gamma Knife	Perfexion	Perfexion	Perfexion
)))
Teletherapy	0	0	0

United States Nu-	S.NRC HDR Bi	rachytherapy Sites
	Event Site	Number of Events
	Breast	1
	Gynecological (mostly vaginal cylinders)	9
	Skin	1
	Bronchus	2



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≪U.S.NRC 35.600 HDR Brachytherapy Observations

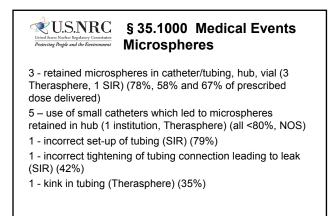
- · Action plans
 - Personnel training, especially when upgrading or changing treatment units
 - Proper timeouts
 - Verification of cylinder placement before, during and after treatment
 - Manufacturer notification

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≪U.S.NRC 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

Protecting People and the EventnementFY2013FY2014FY2015All § 35.100015261418patientsAll Microsphere13231418 pts.166TheraSphere378/12Radioactive Seed Localization120	U.S.NRC States Nuclear Regulatory Commission	35.1000	Medi	cal Events
18 All Microsphere 13 23 14 18 18 SIR-Spheres 10 16 6 TheraSphere 3 7 8/12 Radioactive Seed 1 2 0	Protecting People and the Environment	FY2013	FY2014	FY2015
18 pts. SIR-Spheres 10 16 6 TheraSphere 3 7 8/12 Radioactive Seed 1 2 0	All § 35.1000	15	26	18
TheraSphere 3 7 8/12 Radioactive Seed 1 2 0	All Microsphere	13	23	
Radioactive Seed 1 2 0	SIR-Sphe	eres 10	16	6
1 2 0	TheraSph	nere 3	7	8/12
		1	2	0



VISINRC § 35.1000 Medical Events United States Nuclear Regulatory Commission Protecting People and the Environment 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)



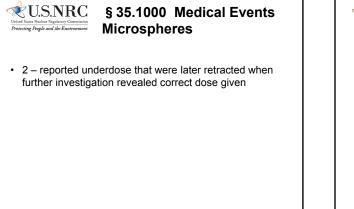
XUSNRC § 35.1000 Medical Events **Microspheres**

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



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U.S.NRC Lief Start Nieder Regeleury Constants Protecting People and the Emrinyment

- 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]

Customer Events – Charl Star Noder Replace Constant Protecting Prople and the Emrinyment

- 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]

US.NRC Wind Youry Way Registery Communication Protecting Proplet and the Environments [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 –

 Lot of Sun Nutur Register Constants
 Lost materials/sources FY15

 [FY14]
 [FY14]

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- 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]

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• Buried pacemaker - 1 [0]

US.NRC Other Events – Protecting Prople and the Every Transmission Protecting Prople and the Every Transmission 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		
Hospital	Residence	Not identified
6 [2]	10 [23]	58 [37]
1 [1]	2 [0]	1 [2]
3 [18]		10 [14]
0 [3]	1 [0]	1 [0]
0 [3]	0 [3]	21 [7]
	Hospital 6 [2] 1 [1] 3 [18] 0 [3]	Hospital Residence 6 [2] 10 [23] 1 [1] 2 [0] 3 [18] 0 [3]

Reports from Agreement States – 18 [12]% AL 81 [85]% CA 1 [1]% FL 0 [1]% NC 1 [2]% DC

≪U.S.NRC Conclusions

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- · 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

U.S.NRC Deticed Enter Neder Regulatory Consultant Protecting People and the Enteriorumment

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

U.S.NRC Valed States Norder Regulatory Commission Protecting People and the Exertironment

- 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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