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

Medical Events Subcommittee Report

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Advisory Committee for the Medical Uses of Isotopes

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Subcommittee Members

- Ronald D. Ennis, M.D. (Chair)
- Richard Green
- Darlene Metter, M.D.
- Michael O'Hara, Ph.D.
- John Suh, M.D.
- Michael Sheetz

Process

- This year, rather than review the details of specific cases, we are reporting on our overview of events over last 3.5 years to discern common themes within each section of 10 CFR Part 35 and across the sections, to inform a discussion of possible ways to decrease medical events (MEs).
- We reviewed the last three reports of this subcommittee (FYs 2014-16) as well as the spring report of Dr. Howe for FY 2017

Summary

- Two overarching themes emerged
  - Performance of a time out immediately prior to administration of radioactive byproduct material, as is done in surgery and other settings, could have prevented some MEs
  - Lack of recent or frequent performance of the specific administration appears to be a contributing factor in a number of cases

35.200 Use of Unsealed Byproduct Material for Imaging and Localization

Medical Events Summary

	2014	2015	2016	2017	Total
Cause					
Wrong drug*	0	3	3	0	6
Wrong dosage	5	0	3	3	11
Wrong patient	1	1	2	0	4
Total	6	4	8	3	21

* In most cases wrong drug was also wrong dosage

21 events over 4 years

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35.200 Use of Unsealed Byproduct Material for Imaging and Localization

How Can These Events Be Prevented?

- Wrong drug: Time out - confirm the order, compare to the prescription
- Wrong dosage: If a dose calibrator is available – measure the activity
- Wrong patient: Time out - Verify patients by two means of identification
- 10/21 preventable if time out had been used

35.300 Use of Unsealed Byproduct Material, Written Directive Required

Medical Event Summary

	2014	2015	2016	2017	Total
WD not done or incorrectly	0	1	0	2	3
Error in delivery (#capsules)	2	3	1	1	7
Wrong dose	0	2	3	0	5
Equipment	1	1	0	0	2
Unauthorized clinic	0	0	1	0	1
Wrong patient	1	0	0	1	2
Total	4	7	5	4	20

Time out could prevent 10-17/20

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35.400 Manual Brachytherapy

Medical Event Summary

	2014	2015	2016	2017	Total
Applicator issue (e.g. movement during implant	1	1	1	0	3
Wrong site implanted (e.g. penile bulb)	3	1	1	1	6
Activity/prescription error (e.g. air kerma vs mCi)	1	2	0	1	4
Prostate Dose	0	4	18	5	27

35.400 Manual Brachytherapy

Medical Event Summary

	2014	2015	2016	2018	Total
Total ME	5	8	20	7	40
"Time out" may have prevented	1	2	0	1	4 (10%)
Lack of experience may have played a role	3	1	1	1	6 (15%)

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35.400 Manual Brachytherapy

Many MEs in this category are no longer categorized as MEs due to change from dose- to activity-based definition.

Lack of experience possibly plays a role in the true MEs of this type, but hard to assess to what degree in each case.

In approximately 25% of cases, a "time out" or enhanced retraining prior to performance of an uncommon procedure might have prevented the ME.

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35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic unit

Medical Event Summary

	2014	2015	2016	2017
Cause				
Wrong position	3	6	1	2
Wrong reference length	2	3	0	2
Wrong plan	1	3	1	0
Wrong dose/source strength	2	0	0	0
Machine malfunction	2	2	3	2
Software failure	0	0	0	2 (9 pts)
Total	10	14	5	8 (14 pts)

37 events over 4 years

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35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic unit

Medical Event Summary

	2014	2015	2016	2017
Location				
Breast	1	1	0	0
Gynecological	5	9	2	7 (14 pts)
Skin	2	1	1	0
Bronchus	1	2	0	0
Prostate	0	0	2	0
Brain	1	1	0	1
Total	10	14	5	8 (14 pts)

GYN tumors most common site of ME

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35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic unit

MEs that may have been prevented by "timeout" (wrong plans or dose)

- 2014 3/10 events
- 2015 3/14 events
- 2016 1/5 events
- 2017 0/8 events

Total 6/37 (16.2%)

35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic unit

MEs caused by "infrequent user"

This is difficult to determine based on information on NMED. If assumption is made about wrong position as surrogate for "infrequent" user

- 2014 3/10 events
- 2015 6/14 events
- 2016 1/5 events
- 2017 2/8 events

Total 12/37 (32.4%)

35.1000 Radioactive Seed Localization

Medical Events Summary

	2014	2015	2016	2017
Total Medical Events	1	1	0	2
Cause:				
Delayed seed removal (patient intervention)	1	1		
Lost seed				1
Wrong implant site				1

35.1000 Gamma Knife® Perfexion™ and Icon™

Medical Events Summary

	2014	2015	2016	2017
Total Medical Events	1	8	3	0
Cause:				
Patient positioning system misalignment by vendor (same site)		8		
Patient setup error			2	
Patient movement			1	
Wrong site (treatment plan)	1			

35.1000 Y-90 Theraspheres

Medical Events Summary

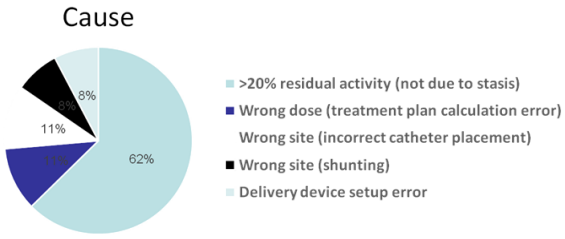
	2014	2015	2016	2017
Total Medical Events	9	8	13	15
Cause:				
> 20% residual activity remaining in delivery device	6	7	9	7
Delivery device setup error			1	2
Wrong dose (treatment plan calculation error)	1		1	4
Wrong site (catheter placement error)	1	1	2	2
Wrong site (shunting)	1			

35.1000 Y-90 SirSpheres

Medical Events Summary

	2014	2015	2016	2017
Total Medical Events	15	10	13	8
Cause:				
> 20% residual activity remaining in delivery device not due to stasis	10	2	9	7
Wrong site (shunting)	2	4		
Delivery device setup error	1	3		
Wrong dose (treatment plan calculation error)	1	1	2	
Wrong site (catheter placement error)	1		2	1

Overview Y-90 Microsphere ME 2014 - 2017



Actions to Prevent 35.1000 Y-90 Microsphere Medical Events

- Review mechanics of Y-90 microsphere delivery device and setup procedures
- Confirm all data and calculations in treatment plan
- Perform “Time Out” to assure all elements of treatment are in accordance with Written Directive

35.1000 Medical Events That May Have Been Prevented by "Time Out"

	RSL	Perfexion/Icon	Y-90 Microspheres
2014	1/2	1/1	3/24
2015	0/1	0/8	2/18
2016	0/1	2/3	3/26
2017	0	0	3/23
Total	1/4 (25%)	3/12 (25%)	11/91 (12%)

35.1000 Medical Events That May Have Been Attributed to Lack of Experience or Infrequent User

	RSL	Perfexion/Icon	Y-90 Microspheres
2014	0/2	0/1	1/24
2015	0/1	0/8	3/18
2016	0/1	2/3	1/26
2017	0	0	2/23
Total	0/4 (0%)	2/12 (17%)	7/91 (8%)

Possible Elements of a "Time Out"

- Identity of patient via two identifiers (e.g. name and DOB)
- Procedure to be performed
- Isotope
- Activity
- Dosage
- Others as applicable
  - units of activity (LDR prostate)
  - anatomic location
  - patient name on treatment plan
  - treatment plan independent second check has been performed
  - reference length (HDR)
  - Implant site location (RSL)

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Possible Elements of Refresher for Infrequent Procedure

- Take review course from professional society
- Read review articles
- Speak to colleague with experience
- Do dry run of procedure with the team
- Review mechanics of device set up and procedure

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Recommendation for Action

The subcommittee recommends the NRC issue an Information Notice alerting AUs to the themes identified herein

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Acronyms

- 10 CFR – Title 10 of the *Code of Federal Regulations*
- AUs – authorized users
- DOB – date of birth
- FY – Fiscal Year
- Gy – Gray
- gyn – gynecological
- HDR – high dose-rate

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Acronyms

- LDR – low dose rate
- mCi – milliCurie
- ME – Medical Event
- RSL – radioactive seed localization
- Y – Yttrium

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