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United States Nuclear Regulatory Commission
Protecting People and the Environment

Medical Events Subcommittee Report

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Advisory Committee on 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.
- Michael Sheetz
- Harvey Wolkov, M.D.

NRC Staff Resource: Donna-Beth Howe, Ph.D.

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Process

- As begun in 2018, every two years the Medical Events Subcommittee will report on our review of events over the last 4 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).
- The Subcommittee reviewed the medical events for FYs 2016-2019.

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Summary

- Two overarching themes remained
  - 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
- One new issue identified
  - Increase complexity of unsealed source administrations of newer agents may be leading to more equipment related MEs

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35.200 Use of Unsealed Byproduct Material for Imaging and Localization

Medical Events Summary

	2016	2017	2018	2019	Total
Cause					
Wrong drug	0	0	0	0	0
Wrong dosage	0	2	0	0	2
Wrong patient	0	1	0	0	1
Extravasation	0	1	0	0	1
Human error	0	0	0	1 (8 patients)	1 (8 patients)
Total	0	4	0	1	5

3/5 possibly preventable by "time out"

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35.300 Use of Unsealed Byproduct Material, Written Directive Required

Medical Events Summary

	2016	2017	2018	2019	Total
WD not done or incorrectly	1	2	1	2	6
Error in delivery (# capsules)	1	1	0	1	3
Wrong dose	1	0	0	0	1
Equipment	0	0	1	4	5
Human Error	1	0	0	1	2
Wrong patient	1	1	0	1	3
Total	4	4	2	9	19

"Time out" could prevent 13/19 = 68%
Emerging increase in equipment issues 5/19 = 26% compared to 10% in last review

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35.400 Manual Brachytherapy

Medical Events Summary

	2016	2017	2018	2019	Total
Applicator issue (e.g. movement during implant	1	0	0	0	1
Wrong site implanted (e.g. penile bulb)	1	1	1	1	4
Activity/prescription error (e.g. air kerma vs mCi, enter wrong activity in planning software)	0	1	0	1	2
Prostate Dose	18	5	11	3*	37
New device	0	0	1	0	1
Total	20	7	13	5	45

*Still using dose-based criteria

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35.400 Manual Brachytherapy

Medical Events Summary

	2016	2017	2018	2019	Total
Total MEs	20	7	13	5	45
"Time out" may have prevented ME	0	1	0	1	2
Lack of experience may have played a role	1	1	1	1	4

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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, although even in 2019, this definition continued to be used for some MEs.
- 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 13% (down from 25% in last review) 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 Events Summary

	2016	2017	2018	2019	Total
Cause					
Wrong position	1	2	3	4	10
Wrong reference length	0	2	1	4	7
Wrong plan	1	0	2	0	3
Wrong dose/source strength	0	0	1	0	1
Machine malfunction	3	2	3	1	9
Software failure	0	2 (9 pts)	0	1	3
Total	5	8 (14 pts)	10	10	33

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

Medical Events Summary

	2016	2017	2018	2019
Location				
Breast	0	0	1	0
Gynecological	2	7 (14 pts)	7	8
Skin	1	0	1	0
Bronchus	0	0	0	0
Prostate	2	0	0	0
Brain	0	1	1	2
Total	5	8 (14 pts)	10	10

GYN tumors were 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)

- 2016 1/5 events
- 2017 0/8 events
- 2018 3/10 events
- 2019 3/10 events

Total: 7/33 (21.2%) compared to 16% on last review

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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 in NMED. If assumption is made about wrong position as surrogate for "infrequent" user.

- 2016 1/5 events
- 2017 2/8 events
- 2018 1/10 events
- 2019 1/10 events

Total: 5/33 (15.2%) compared to 32% on last review

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35.1000 Radioactive Seed Localization

Medical Events Summary

	2016	2017	2018	2019
Total Medical Events	1	0	1	0
Cause:				
Delayed seed removal (patient intervention)	1		1	
Lost seed				0
Wrong implant site				0

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35.1000 Intravenous Cardiac Brachytherapy

Medical Events Summary

	2016	2017	2018	2019	Total
Did not follow proper procedure	0	0	0	1	1
Tortuous vessel anatomy	0	0	1	1*	2
Catheter issue	0	0	1	0	1
Total	0	0	2	1	4

*AU felt this is “patient intervention”
No time out issues
Difficult to assess the unfamiliarity issue, but possibly played a role in some

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35.1000 Gamma Knife® Perfexion™ and Icon™

Medical Events Summary

	2016	2017	2018	2019
Total Medical Events	3	0	1	0
Cause:	0	0	0	0
Back-up battery power source failure	0	0	1	0
Patient setup error	2	0	0	0
Patient movement	1	0	0	2
Wrong site (treatment plan)	0	0	0	0

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35.1000 Y-90 Theraspheres

Medical Events Summary

	2016	2017	2018	2019	Total
Total Medical Events	13	15	14	15	57
Cause:					
> 20% residual activity remaining in delivery device	9	7	11	9	36
Delivery device setup error	1	2	2	1	6
Wrong dose (treatment plan calculation error)	1	4	0	1	6
Wrong site (catheter placement error)	2	2	0	0	4
Wrong dose vial selected			1	4	5

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35.1000 Y-90 SirSpheres

Medical Events Summary

	2016	2017	2018	2019	Total
Total Medical Events	13	8	7	11	39
Cause:					
> 20% residual activity remaining in delivery device not due to stasis	9	7	2	8	26
Wrong dose (treatment plan calculation error)	2	0	2	0	4
Wrong site (catheter placement error)	2	1	2	2	7
Wrong site (WD error)	0	0	1	1	2

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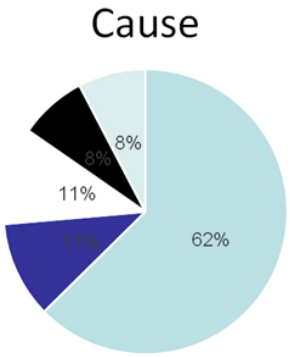
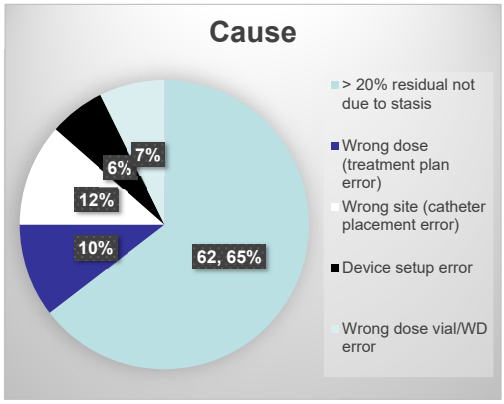
Overview Y-90 Microsphere MEs

FY2014 – 2017 N=91



FY2016 – 2019 N=96



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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

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

	RSL	Perfexion/Icon	Y-90 Microspheres
2016	0/1	2/3	3/26
2017	0	0	3/23
2018	0/1	0/1	4/21
2019	0	0/2	7/26
Total	0/2	2/6 (33%)	17/96 (18%)

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

	RSL	Perfexion/Icon	Y-90 Microspheres
2016	0/1	2/3	1/26
2017	0	0	2/23
2018	0/1	0/1	2/21
2019	0	0/2	1/26
Total	0/2 (0%)	2/6 (33%)	6/96 (6%)

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Possible Elements of a "Time Out"

- Identity of patient via two identifiers (e.g., name and DOB)
- Procedure to be performed
- Isotope
- Activity
- Dosage – second check of dosage calculation and that the WD and dosage to be delivered are identical

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Possible Elements of a "Time Out" cont'd.

- 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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Subcommittee Response to Findings

- The subcommittee recommended that the NRC staff issue an Information Notice alerting Authorized Users to the themes identified herein.
- IN-19-07, Methods to Prevent Medical Events, was published on August 26, 2019. (ADAMS Accession No. ML19240A450)

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Acronyms

- 10 CFR – Title 10 of the *Code of Federal Regulations*
- AUs – authorized users
- FY – Fiscal Year
- gyn – gynecological
- HDR – high dose-rate
- LDR – low dose rate
- mCi – milliCurie
- ME – Medical Event
- RSL – radioactive seed localization
- Y-90 – yttrium-90

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