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Medical Events Subcommittee Report

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Advisory Committee on the Medical Uses of Isotopes

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Subcommittee Members

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Subcommittee Charge

- Review Medical Events (MEs) to advise the Advisory Committee on the Medical Use of Isotopes (ACMUI) and United States Nuclear Regulatory Commission (NRC) about emerging trends that may need regulatory attention.

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Background

- The NRC and ACMUI review MEs that occur throughout the country on a regular basis.
- MEs occur when radioactive material use in healthcare results in unexpected radiation dose to patients. (Please refer to 10 CFR 35 Subpart M – Reports and more specifically 10 CFR 35.3045 – Report and Notification of a Medical Event for more information.)
- The Medical Events Subcommittee of the ACMUI reviews the data to analyze the nature of medical events, identify emerging trends and provide recommendations to the ACMUI and NRC.

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Medical Event Review

- FY22 – October 1, 2022 to September 30, 2023
- FY23 – October 1, 2023 to September 30, 2024

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New Methodology

- Medical Event Classification System
  - Equipment Failure – device, hardware or software
  - Process Error – errors caused by inadequate procedures or policies and/or failure to follow
  - Human Error – process and/or checklist not followed
  - Emerging Medical Conditions – patient factors that affect procedure or treatment
  - Insufficient Information Provided – provided data from licensee is inadequate

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10 CFR 35.200

- Process Errors
  - Wrong drug
  - Wrong dosage
  - Wrong patient

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10 CFR 35.300

- Process Errors
  - WD not done or incorrectly prepared
  - Error in delivery
  - Wrong dose
  - Wrong patient
  - Wrong drug

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10 CFR 35.400

- Equipment Failure
  - Applicator issues
  - Eye plaques dislodged
- Process Errors
  - Activity/prescription error
  - Prostate dose
  - Wrong source
  - Wrong patient

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10 CFR 35.400 cont.

- Human Errors
  - Wrong site
- Emerging Medical Conditions
- Insufficient Information Provided

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10 CFR 35.600

- Equipment Failure
  - Equipment/applicator malfunction
  - Software/hardware failure
- Process Errors
  - Wrong reference length
  - Wrong plan
  - Wrong dose/source strength
  - Treatment planning

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10 CFR 35.600 cont.

- Human Errors
  - Wrong position
  - Human errors as previously reported
- Emerging Medical Conditions
- Insufficient Information Provided

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10 CFR 35.1000 – Gamma Knife

- Equipment Failure
  - Back-up battery power source failure
  - Patient motion management system failure
  - Device malfunction
- Process Errors
  - Patient set-up error
  - Patient movement
  - Wrong site (treatment plan)

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10 CFR 35.1000 – Gamma Knife cont.

- Human Errors
  - Wrong site (human error shifting of co-registration images)
- Emerging Medical Conditions
- Insufficient Information Provided

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10 CFR 35.1000 – TheraSphere

- Process Errors
  - >20% residual activity in line/device
  - Delivery device set-up error
  - Wrong dose (treatment plan calculational error)
  - Wrong site (catheter placement error & size)
  - Wrong dose vial selected
  - Wrong dose (calibrations error)
  - Insufficient microsphere dispersal as recommended by manufacturer

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10 CFR 35.1000 – Sir-Spheres

- Process Errors
  - >20% residual activity in line/device
  - Delivery device set-up error
  - Wrong dose (treatment plan calculational error)
  - Wrong site (catheter placement error & size)
  - Wrong dose vial selected
  - Wrong dose (calibrations error)
  - Insufficient microsphere dispersal as recommended by manufacturer
  - Wrong site (WD error)

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35.200 Use of Unsealed Byproduct Material for Imaging and Localization

Medical Events

	2019	2020	2021	2022	2023	2024	Total
Event Type							
Equipment Failure	0	0	0	0	0	0	0
Process Error	0	0	4	0	1	0	5
Human Error	1	0	0	0	0	0	1
Total	1	0	4	0	1	0	6

35.200 Use of Unsealed Byproduct Material for Imaging and Localization

Medical Events Summary

One event in 2023 involving:

- Inadequate communication
- Insufficient AU oversight
- Lack of training

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35.300 Use of Unsealed Byproduct Material, Written Directive Required

Medical Events

	2019	2020	2021	2022	2023	2024	Total
Event Type							
Equipment Failure	4	0	2	1	1	0	8
Process Error	4	0	5	5	8	5	27
Human Error	1	2	3	4	2	2	14
Total	9	2	10	10	11	7	49

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35.300 Use of Unsealed Byproduct Material, Written Directive Required

Medical Events – Process Errors

Event Type	2023	2024	Total
Incorrect Dose Delivered	1	0	1
Failure to Ensure Eq. in Working Order	1	1	2
Failure to Follow Manufacturer Recs	2	0	2
Failure to Identify Correct RP	1	0	1
Failure to Flush Adequately	2	0	2
Failure to Verify WD was Accurate	1	1	2
Outdated & Incorrect Formula	0	2	2
Insufficient Information	0	1	1
Total	8	5	13

35.300 Use of Unsealed Byproduct Material, Written Directive Required

Medical Events – Human Errors

Event Type	2023	2024	Total
Failure to Follow Written Directive	2	1	3
Failure to Verify Activity in Dose Calibrator	0	1	1
Total	2	2	4

35.300 Use of Unsealed Byproduct Material, Written Directive Required

Medical Events Summary

8 events in 2023 involving process errors

- these events may have been avoidable if a procedure-specific process checklist/“time out” was used

2 events in 2023 involving human errors

- both would have benefited from computerized order entry and/or bar coding

5 events in 2024 involving process errors

- these events may have been avoidable if a procedure-specific process checklist/“time out” was used

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35.400 Manual Brachytherapy

Medical Events

Event Type	2019	2020	2021	2022	2023	2024	Total
Equipment Failure (applicator issue (e.g. jam, eye plaque dislodged)	0	2	0	1	1	0	4
Process Error	4	1	2	0	1	0	8
Human Error	1	2	2	0	0	0	5
Emerging Patient Conditions	0	1	0	0	1	1	3
Insufficient Information Provided	0	0	0	0	0	0	0
Total	5	6	4	1	3	1	20

35.400 Manual Brachytherapy

Medical Events – Process Errors

	2023	2024	Total
Incorrect Number of Seeds Implanted	1	0	1
Total	1	0	1

35.400 Manual Brachytherapy

Medical Events Summary

1 event in 2023 involving an equipment failure

- eye plaque shifted (no additional information)

1 event in 2023 involving a process error

- these events may have been avoidable if a procedure-specific process checklist/"time out" was used

2 events involved emerging patient conditions (one each year)

- unavoidable due to patient condition and safety

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

Medical Events

Event Type	2019	2020	2021	2022	2023	2024	Total
Equipment Failure	2	2	1	2	0	1	8
Process Error	4	4	3	4	7	4	26
Human Error	4	7	1	5	1	1	19
Emerging Patient Conditions	0	0	0	0	0	0	0
Insufficient Information Provided	0	0	0	0	0	0	0
Total	10	13	5	11	8	6	53

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

Medical Events – Process Errors

	2023	2024	Total
Vaginal Cylinder Shifted	1	0	1
Incorrect Treatment Plan	2	2	4
Wrong Applicator	1	0	1
Wrong Catheter Channels	1	1	2
Inadequate Maintenance	1	1	2
Stretcher Malfunction	1	0	1
Total	7	4	11

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

Medical Events – Human Errors

	2023	2024	Total
Wrong Site	1	0	1
Wrong Transfer Tubes	0	1	1
Total	1	1	2

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

Medical Events by Location

	2019	2020	2021	2022	2023	2024	Total
Location							
Breast	0	1	0	0	0	1	2
Gynecological	8	10	4	2	6	3	33
Skin/neck	0	2	1	5	1	0	9
Bronchus	0	0	0	0	0	0	0
Prostate	0	0	0	0	1	0	1
Brain	2	0	0	0	0	0	2
Bone	0	0	0	0	0	1	1
Unknown	0	0	0	4 (7 patients)	0	1	5 (7 patients)
Total	10	13	5	11 (7 patients)	8	6	53 (7 patients)

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

Medical Events Summary

1 event in 2024 involving an equipment failure

- timer failed

7 events in 2023 and 4 events in 2024 involved process errors

- these events may have been avoidable if a procedure-specific process checklist/“time out” was used

2 events involved human errors with one event in 2023 and one event in 2024

- these events may have been avoidable if a procedure-specific process checklist/“time out” was used
- improved training may have prevented these MEs

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35.1000 Radioactive Seed Localization

Medical Events

	2019	2020	2021	2022	2023	2024
Total Medical Events	1	0	1	1	1	0
Cause:						
Delayed seed removal (patient intervention)	1	0	0	0	0	0
Delayed seed removal (failure to explant)	0	0	0	0	1	0
Lost seed	0	0	0	0	0	0
Wrong implant site	0	0	0	0	0	0
Seed migration	0	0	1	1	0	0

35.1000 Radioactive Seed Localization

Medical Events Summary

1 event in 2024 involved a process error

- verification of seed removal with a gamma surgical probe would have prevented the ME
- this event may have been avoidable if a procedure-specific process checklist/“time out” was used
- improved training may have prevented this ME

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35.1000 Intravenous Cardiac Brachytherapy

Medical Events

	2019	2020	2021	2022	2023	2024	Total
Process Error	1	0	0	0	0	1	1
Tortuous vessel anatomy	1*	0	0	0	0	0	1
Catheter issue	0	1	0	0	0	0	1
Total	2	1	0	0	1	0	4

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35.1000 Intravenous Cardiac Brachytherapy

Medical Events Summary

1 event in 2024 involved a process error where the source was placed at the wrong site

- this event may have been avoidable if a procedure-specific process checklist/“time out” was used
- improved training may have prevented this ME

35.1000 Gamma Knife® Perfexion™ Icon™ and Esprit™

Medical Events

	2019	2020	2021	2022	2023	2024	Total
Total Medical Events	2	2	0	2	1	1	8
Event Type							
Equipment Failure	0	0	0	1	1	0	2
Process Error	2	1	0	0	0	1	4
Human Error	0	1	0	1	0	0	2
Emerging Patient Conditions	0	0	0	0	0	0	0
Insufficient Information Provided	0	0	0	0	0	0	0

35.1000 Gamma Knife® Perfexion™ Icon™ and Esprit™

Medical Events – Equipment Failure

	2023	2024	Total
Back-up Battery Power System Failure	0	0	0
Patient Motion Management System Failure	0	0	0
Device Malfunction	1	0	1
Total	1	0	1

35.1000 Gamma Knife® Perfexion™ Icon™ and Esprit™

Medical Events – Process Errors

	2023	2024	Total
Patient Set-Up Error	0	0	0
Patient Movement	0	0	0
Wrong Site/Treatment Plan	0	1	1
Total	0	1	1

35.1000 Gamma Knife® Perfexion™ Icon™ and Esprit™

Medical Events Summary

1 event in 2023 involving an equipment failure
- worn sector drive

1 event in 2024 involved a process error (wrong location treated)
- this event may have been avoidable if a procedure-specific process checklist/"time out" was used

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35.1000 ^{90}Y TheraSphere

Medical Events

	2019	2020	2021	2022	2023	2024	Total
Total Medical Events	15	15	23	23	24	30	130
Event Type							
Equipment Failure	0	0	0	0	0	0	0
Process Error	15	15	23	23	22	28	126
Human Error	0	0	0	0	0	0	0
Emerging Patient Conditions	0	0	0	0	0	1	1
Insufficient Information Provided	0	0	0	0	2	1	3

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35.1000 ^{90}Y TheraSphere

Medical Events – Process Errors

	2019	2020	2021	2022	2023	2024	Total
Total Medical Events	15	15	23	23	22	28	126
Event Type							
> 20% residual activity remaining in delivery device/leakage	9	12	10	2	9	7	49
Delivery device set-up error	1	1	1	0	0	4	7
Wrong dose (treatment plan calculation error)	1	0	0	3	1	2	7
Wrong site (catheter placement error & size)	0	2	1	7	4	5	19
Wrong dose vial selected	4	0	1	1	1	1	8
Wrong dose (calibration error)	0	0	3	1	0	0	4
Insufficient microsphere dispersal as recommended by manufacturer	0	0	7	9	7	9	32

35.1000 ^{90}Y TheraSphere

Medical Events Summary

22 events in 2023 and 25 events in 2024 involved process errors

- these events may have been avoidable if a procedure-specific process checklist/“time out” was used

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35.1000 ^{90}Y Sir-Spheres

Medical Events

	2019	2020	2021	2022	2023	2024	Total
Total Medical Events	11	8	18	9	9	3	58
Event Type							
Equipment Failure	0	0	0	0	1	0	1
Process Error	11	8	18	9	7	3	56
Human Error	0	0	0	0	0	0	0
Emerging Patient Conditions	0	0	0	0	0	0	0
Insufficient Information Provided	0	0	0	0	1	0	1

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35.1000 ^{90}Y Sir-Spheres

Medical Events – Process Errors

	2019	2020	2021	2022	2023	2024	Total
Total Medical Events	11	8	18	9	7	3	56
Cause:							
> 20% residual activity remaining in delivery device/leakage	8	8	2	1	2	1	22
Wrong dose (treatment plan calculation error)	0	0	2	1	0	0	3
Wrong site (catheter placement error & defective catheter)	2	0	4	0	0	0	6
Wrong site (WD error)	1	0	1	1	1	0	4
Failed to follow WD	0	0	0	0	3	1	4
Insufficient microsphere dispersal as recommended by manufacturer	0	0	9	6	1	1	17

35.1000 ^{90}Y Sir-Spheres

Medical Events Summary

1 event in 2023 involving an equipment failure

- device failure

7 events in 2023 and 3 events in 2024 involved process errors

- these events may have been avoidable if a procedure-specific process checklist/“time out” was used

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Actions to Prevent 35.1000 ^{90}Y Microsphere Medical Events

- Ensure familiarity with the mechanics of ^{90}Y microsphere delivery device and setup procedures
- Confirm all data and calculations in treatment plan
- Develop a procedure-specific process checklist to ensure procedures are completed as planned
- Perform “Time Out” appropriately to assure all elements of treatment are in accordance with WD

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Possible Elements of a Procedure-Specific Process Checklist/"Time Out"

- Identity of patient via two identifiers (e.g. name and DOB)
- Procedure to be performed
- Radiopharmaceutical
- Activity
- Dosage – second check of dosage calculation and that the WD and dosage to be delivered are identical
- 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)
- Review every procedure post-treatment (to verify a ME has not occurred and respond appropriately if necessary)

See Generic Process Checklist https://www.nrc.gov/docs/ML2517/ML25177A051.pdf

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Medical Event Comprehensive Summary

- 10 CFR 35.200
  - Incidence remains low
  - Improved communication and AU oversight may assist in maintaining events low
- 10 CFR 35.300
  - Medical events are caused primarily via process errors, but human errors are still present
  - Decrease in medical events observed in FY 2024
- 10 CFR 35.400
  - Process errors are the most significant event type
  - Human errors and emerging patient medical conditions are important factors

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Medical Event Comprehensive Summary

- 10 CFR 35.600
  - Process errors are the most significant event type
  - Human errors, equipment failure and emerging patient medical conditions are important factors
  - Medical events involving GYN procedures are the most common
  - Decreasing trend
- 10 CFR 35.1000 – Radioactive Seed Localization - infrequent
- 10 CFR 35.1000 Intravenous Cardiac Brachytherapy - infrequent

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Medical Event Comprehensive Summary

- 10 CFR 35.1000 – Gamma Knife
  - Low incidence
  - Process errors are the most significant
  - Equipment failure and human errors are possible but remain rare
- 10 CFR 35.1000 – TheraSphere
  - Medical events are almost always process errors
  - Increasing trend
- 10 CFR 35.1000 – Sir-Spheres
  - Medical events are almost always process errors
  - Decreasing trend

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Medical Event Comprehensive Summary

- Possible preventative measures
  - Procedure-specific process checklists/“Time Outs” including appropriate execution
  - Please refer to the USNRC ACMUI report titled “Development of a Generic Process Checklist to Help Reduce Medical Events”
  - Computerized order entry and bar coding
  - Improved communication
  - AU oversight
  - Training

https://www.nrc.gov/docs/ML2517/ML25177A051.pdf

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Acronyms

- 10 CFR – Title 10 of the *Code of Federal Regulations*
- ACMUI – advisory committee on the medical use of isotopes
- AUs – authorized users
- FY – fiscal year
- GYN – gynecological
- HDR – high dose-rate
- LDR – low dose rate
- ME – medical event
- NRC – Nuclear Regulatory Commission
- RSL – radioactive seed localization
- WD – written directive
- Y – Yttrium