Status of Medical Events FY 2025

Daniel DiMarco
Medical Radiation Safety Team
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Purpose of Medical Event Reporting

- Medical event reporting helps to identify deficiencies in the safe use of radioactive material and ensures that corrective actions are taken to prevent recurrence.
- A medical event may indicate a potential problem in a medical facility's use of radioactive materials.
- It does not necessarily result in harm to the patient.
- Medical event reporting allows the NRC to determine if other licensees might be experiencing the same or similar challenges. The NRC assesses trends or patterns, identifies generic issues or concerns, and recognizes any inadequacy or unreliability of specific equipment or procedures.

Immediate Reporting Requirements

- A written report must be submitted within 15 days after discovery and must include
  - Licensee's name
  - Name of prescribing physician
  - Brief description of event
  - Why the event occurred
  - The effect, if any, on the individual(s) who received the administration
  - What actions, if any, have been taken or are planned to prevent recurrence
- Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.
- Report should not include patient's name. Separate annotated copy of the report should be provided with patient name, identifying number, and copy of annotated report to referring physician.

Reporting Best Practices

- The NRC uses medical event reports to look for trends and generic issues.
- Provide enough detail that an uninvolved individual would have a full understanding of the event.
- Do not assume the reader knows all associated regulations or current standard protocols.
- Helpful details include:
  - Manufacturer, model, or specifications of supporting equipment associated with the event such as IV pump or gauge size.
  - Relevant information that preceded the event.
  - What staff was present.
  - How the event was identified.
  - Include short and long term corrective actions and how they are linked to the event.
  - Clearly highlight if the event or corrective actions involve a common industry-wide practice or procedure.

Medical Events FY 2020 - 2025

	FY20	FY21	FY22	FY23	FY24	FY25
35.200	0	4	0	1	0	1
35.300	2	10	10	11	7	10
35.400	6	4	1	3	1	0
35.600	13	5	11 (40*)	8	6	5
35.1000	27	41	34	36	34	26 (31*)
Total	48	64	56	59	48	42

* The total number of patients involved if greater than the number of reports

Medical Events 2025

35.200 Medical events	**1**
I-123	1

35.200 I-123

- Patient Overdose [250129]
  - Prescribed 7.4 MBq (200 µCi), administered 73.26 MBq (2000 µCi)
  - Dosage was miscommunicated to the technologist and mislabeled on the vial
  - Additionally, the technologist did not verify or crosscheck the units before confirming the dosage
  - Dose to the thyroid was calculated to be 174 cGy
  - No adverse effects are expected, the licensee was expecting to treat a toxic nodule on the thyroid with I-131 at a later date
  - Corrective actions included mandating that external orders involving I-123 be sent by fax and implementing additional reviews when accepting doses from external radiopharmacies
  - Additionally, the licensee is working to implement an electronic tracking system

Medical Events 2025

35.300 Medical events	**10**
I-131	1
Ac-225	1
Lu-177	8

35.300 I-131

- Patient Overdose [250042]
  - Prescribed 555 MBq (15 mCi), administered 666 MBq (18 mCi)
  - The activity of the I-131 capsules was measured in a dose calibrator
  - This dose was then compared to the prescribed dose and then manually calculated to determine if it was within 20% of the prescribed dose
  - The NMT incorrectly calculated the administered dose
  - No adverse effects were expected
  - Corrective actions included transition of the paper-based WD to an electronic form with automatic calibration of measured to prescribed dose

35.300 Ac-225

- Patient Underdose [250094]
  - Prescribed 10.69 MBq (289 µCi), administered 111 kBq (3 µCi)
  - Infusion pump failed during an administration of an Ac-225 PSMA research targeted alpha radionuclide therapy
  - At the end of the infusion the syringe shield was lifted and a technologist noticed that Ac-225 had leaked into the shield from the stopcock
  - No contamination was found and the contaminated equipment was surveyed and held for decay
  - No adverse effects were expected
  - Corrective actions included establishment of a new administration workflow

35.300 Lu-177

- Wrong Drug [250304]
  - Prescribed 7.4 GBq (200 mCi) Lu-177, administered 5.77 MBq (156 µCi) Ra-223
  - Licensee estimated dose to whole body to be 13.3 cSv (rem) and 665 cSv (rem) to bone marrow
  - No adverse effects are expected
  - Root cause was determined to be human error, the unit doses of both drugs were stored on the same rack and the licensee failed to confirm the correct dose during a time out
  - Corrective actions included procedural changes and additional personnel training
  - Additionally, the NMT and AU are now required to verify the correct patient via two forms of identification and verify that the dose matches the WD

35.300 Lu-177

- Patient Overdose [250075]
  - Prescribed 5.9 GBq (160 mCi), administered 7.4 GBq (200 mCi)
  - Investigations determined that the NMT did not review the WD before administering the dose due to distractions in the department
  - No adverse effects were found in patient follow-up visits
  - Corrective actions included new reviews of WDs before the patient arrives as well as another review before administration to confirm drug, dose, and patient

35.300 Lu-177

- Patient Underdose [250126]
  - Prescribed 6 GBq (162 mCi), administered 1.8 GBq (49 mCi)
  - During the procedure, the patient's creatinine level was discovered to be significantly elevated
  - The procedure was stopped and the patient was transferred to the emergency room
  - No adverse effects are expected
  - Root cause was determined to be human error
  - Corrective actions included procedure modifications

35.300 Lu-177

- Patient Underdose [250378]
  - Prescribed 7.4 GBq (200 mCi), administered 2.96 GBq (80 mCi)
  - During treatment, an NMT noticed that a small amount of radiopharmaceutical had leaked on the absorbent pads and the patient's arm
  - RSO was contacted, the patient was decontaminated, and the waste was collected to estimate the dose delivered
  - Investigation found that increased infusion pump pressure loosened a non-secured IV connection, causing the leak
  - The licensee scheduled a fifth dose to compensate for this underdose
  - Corrective actions included updating the standard operating procedures to double verify line connections and continuous monitoring of the patient during the procedure

35.300 Lu-177

- Patient Underdose [250221]
  - Patient prescribed 7.4 GBq (200 mCi), received 3.27 GBq (88.4 mCi)
  - During treatment, a slow obscured leak was discovered in the side port of a three-way stopcock
  - After adjusting the cap, the remaining dose was pushed by hand
  - Surveys of the contaminated absorbent material and patient revealed the amount of dose that was not delivered
  - Root cause was determined to be incorrect delivery set up and insufficient training
  - A cap provided with the three-way stopcock was designed to maintain sterility and not to seal the side port
  - Additionally, a last-minute need for extension tubing required a repriming of the tubing, and the syringe pump was turned off
  - Corrective actions included retraining by the manufacturer, proctoring of the next two treatments, discontinuing use of the cap provided with the stopcock, and development of a new administration checklist

35.300 Lu-177

- Patient Underdose [250213]
  - Patient prescribed 7.4 GBq (200 mCi), received 4.33 GBq (117.1 mCi)
  - Licensee staff noted difficulties with initiating flow using the gravity delivery system
  - Attempts to correct the problem were unsuccessful, the treatment was halted, and the equipment was surveyed to estimate the delivered dose
  - No adverse effects were expected
  - Post-treatment investigations determined that all manufacturer's procedures were correctly followed

35.300 Lu-177

- Patient Underdose [250193]
  - Prescribed 7.4 GBq (200 mCi), administered 4.86 GBq (131.3 mCi)
  - Post-treatment imaging showed that the dose delivered to the target organ was below the intended dose
  - The AU determined that no adverse effects were expected and that the dose delivered was adequate
  - No changes to the patient's treatment schedule were implemented
  - State investigation did not determine a root cause and that the dose was administered in accordance with protocol
  - No corrective actions were proposed

35.300 Lu-177

- Patient Underdose [250133]
  - Patient prescribed 7.4 GBq (200 mCi), received 4.81 GBq (130 mCi)
  - During treatment, backflow was identified in the three-way stopcock that leaked onto the absorbent pads under the patient's arm
  - Surveys of the material were used to estimate the administered dose
  - Root cause was determined to be human error and inadequate training
  - Staff being trained used the syringe shield backwards, allowing the set screw to put too much pressure on the syringe, causing leakage
  - Corrective actions included improved training

Medical Events 2025

35.600 Medical events	**5**
HDR	5

35.600 HDR

- Wrong Site [250333]
  - 278.98 GBq (7.54 Ci) Ir-192 HDR unit
  - Prescribed 4,000 cGy (rad) over 8 fractions, received one 500 cGy (rad) fraction to wrong lesion
  - Brain mask for immobilization was made for the treatment of a scalp lesion
  - Mask had an opening for placement of the skin applicator
  - AU mistakenly identified a different lesion than the intended lesion on the treatment day
  - The Radiation Oncologist was not present during the same-day patient treatment simulation and positioned the mask to treat the wrong lesion
  - Root cause was determined to be human error
  - Corrective actions included revision of procedures to require an RO to be present at all HDR skin simulations

35.600 HDR

- Wrong Site [250229]
  - 384.8 GBq (10.4 Ci) Ir-192 HDR unit
  - Patient was being treated for skin cancer on the left temple
  - Prescribed 4,000 cGy (rad), in 10 fractions of 400 cGy(rad)
  - The first fraction was mistakenly given to the left cheek and was not noticed until the patient returned for the second fraction
  - Root cause was determined to be human error and failure to follow the WD
  - Miscommunication with a dermatology referral caused confusion in determining the correct treatment site
  - Corrective actions included procedure revisions to delay administration if the treatment site is unclear and asking the patient to point to the treatment site prior to administration

35.600 HDR

- Patient Underdose [250289]
  - Patient prescribed 600 cGy (rad) a fraction for 5 fractions, delivered 260 cGy (rad) for fraction 3
  - AU placed the cylinder in the correct location prior to treatment and verified the location
  - Following the treatment, the AU noticed the cylinder had shifted up to 1 cm and was no longer secured
  - The time of the shift was not able to be determined but the dose estimate was calculated based on an immediate shift
  - The AU does not believe any other organs were exposed above regulatory limits
  - The missing dose was made up in future fractions
  - Corrective actions included a review of equipment and alternatives to the licensees practices

35.600 HDR

- Patient Underdose [25100, 25101]
  - 335.59 GBq (9.07 Ci) Ir-192 HDR unit
  - Patient prescribed to 2,700 cGy to prostate in 2 fractions
  - Licensee entered incorrect catheter length into procedure software, resulting in a 5 cm distance from intended treatment site
  - Prostate received 0 dose, rectum received 60% of expected dose
  - Additional fraction to treat the prostate was scheduled
  - Corrective actions included review of catheter length by the physicist and physician and adding the catheter length as a check item during the time out
  - Additionally the catheter length in the treatment planning notes sheet was corrected
  - Each fraction was given it's own WD, leading to two events

Medical Events 2025

35.1000 Medical events	**26**
GSR	1
Y-90 Microspheres	
– Eye90 microspheres®	1
– TheraSphere™	18
– SIR-Spheres®	6

35.1000 Gamma Stereotactic Radiosurgery

- Patient Underdose [250146]
  - Patient was prescribed 8,000 cGy (rad) to trigeminal nerve, received 2,000 cGy (rad)
  - During treatment the unit experienced an electrical sensor failure after 12.47 minutes of treatment time
  - All sources were automatically retracted, the patient was removed from the unit bore by the robotic couch, and shielding doors closed
  - The unit was repaired by the manufacturer the next day and the patient's treatment was completed sucessfully

35.1000 Eye90 microspheres®

- Patient Underdose [250132]
  - Prescribed 1.89 GBq (51mCi), received between 0.851 GBq and 1.13 GBq (23 and 30.6 mCi)
  - During treatment the licensee noted droplets of liquid on the microcatheter
  - Posttreatment surveys revealed activity on staff shoe covers and scrubs as well as contamination on various drapes and delivery equipment
  - Surveys of waste and contaminated items gave an estimate of the delivered dose

35.1000 Eye90 microspheres®

- Patient Underdose [250132] (cont.)
  - Investigations determined the root cause to be a buildup of pressure in the vial, leading to overflow into a cavity in the delivery device
  - Additionally, shielding over the vial obscured the leak
  - After the procedure the microspheres then spilled out when collecting equipment for disposal
  - The physician was unaware of the failure and followed all procedures and sponsor guide checklists
  - Corrective actions included placing the trial on hold, and eventual withdrawal of the study, more stringent training requirements for future new therapies, and training requirements for the full team involved in new therapies

35.1000 TheraSphere™

- Patient Underdose [250201]
  - Patient prescribed 2 doses of 814 MBq (22 mCi) each, delivered 130.39 MBq (3.54 mCi) and 123.95 MBq (3.35 mCi)
  - Root cause was determined to be human error
  - Order was sent for the correct doses but a two week decay time was entered instead of one week, resulting in the lower doses administered
  - Additionally, documentation of received activity was separate from the prescribed activity
  - Corrective actions included procedure modifications to establish agreement between received and prescribed activity
  - Additionally, the WD was updated to include all information in one document

35.1000 TheraSphere™

- Patient Underdose [250371]
  - Patient prescribed 3.36 GBq (90.7 mCi), received 2.49 GBq (67.2 mCi)
  - Physician noted resistance while delivering the microspheres
  - Initial investigations appeared to show a defect in the kit, resulting in microsphere clumping and high back pressure in the IV line
  - Delivery kit was returned to the manufacturer for investigation
  - Physician noted that the treatment was therapeutically acceptable

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- Patient Underdose [250360]
  - Patient prescribed 2.45 GBq (66.15 mCi), delivered 1.24 GBq (33.51 mCi)
  - The microcatheter was placed successfully but because of the patient's height the tubing selected was not long enough to reach the delivery system
  - Licensee decided to add extension tubing and a stopcock since the microcatheter placement was ideal
  - The manufacturer rep on site did not object to the change
  - Post-treatment, a significant amount of microspheres was observed in the added extension and stopcock
  - Corrective actions included discontinuing use of tube extensions and additional personnel training

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- Patient Underdose [250290]
  - Patient prescribed 438.56 MBq (11.853 mCi), received 176.82 MBq (4.779 mCi)
  - Root cause was determined to be microsphere clumping that was not alleviated with repositioning or saline flushes
  - During investigation, 2 other underdoses were discovered with this patient
  - Prescribed 222 MBq (6 mCi) and 289.71 MBq (7.83 mCi), received 151.7 MBq (4.1 mCi) and 166.5 MBq (4.5 mCi) respectively

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- Patient Underdose [250290] (cont.)
  - Root cause was determined to be the same in these other two underdoses, including small treatment volumes and narrow vessel size
  - Corrective actions included discontinuing use of the microcatheter, review of the delivery system, and additional staff training
  - Additionally, a review of the microsphere delivery process is ongoing and consideration of a new, higher pressure, system is being considered

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- Patient Underdose [250279]
  - Patient prescribed 1.75 GBq (47.42 mCi), received 1.36 GBq (36.81 mCi)
  - AU decided to use a smaller than recommended catheter due to treatment area
  - No adverse effects were expected
  - No corrective actions were proposed

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- Patient Underdose [250220]
  - Patient prescribed 3.4 GBq (91.84 mCi), delivered 2.32 GBq (62.78 mCi)
  - Licensee noticed a spill during treatment from the delivery system
  - Contaminated area was cleaned and released
  - No root cause was identified
  - Corrective actions included providing additional training to the AU involved with the incident

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- Patient Underdose [250187]
  - Prescribed 640.1 MBq (17.3 mCi), received 240.13 MBq (6.49 mCi)
  - Root cause was determined to be either small vessel size or obstruction of the catheter
  - Patient may be scheduled for additional treatment
  - No corrective actions were taken

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- Patient Underdose [250178]
  - Patient prescribed 1.38 GBq (37.3 mCi), received 0.459 GBq (12.4 mCi)
  - Licensee suspected mechanical failure
  - Delivery kit was returned to the manufacturer for analysis
  - Root cause was determined to be catheter blockage or crimping of the catheter lumen as most of the microspheres were held up in the vial
  - Corrective actions included more training on normal saline flow during the priming of catheters and for physicians to be more cognizant of catheter manipulation to minimize crimping potential

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- Patient Underdose [250156]
  - Patient prescribed 630.11 MBq (17.03 mCi), received 290.08 MBq (7.84 mCi)
  - Physician stated that the patient tolerated the procedure well but noted tortuous anatomy and increased resistance during the first flush
  - Post-treatment measurements indicated lower than expected readings from the patient and calculations were made to estimate the administered activity
  - Patient was successfully treated with an additional dose
  - Root cause was determined to be kinking of the catheter due to tortuous anatomy as well as not flushing with the recommended amount of saline

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- Patient Underdose [250283]
  - Patient prescribed 843.6 MBq (22.8 mCi), received 462.5 MBq (12.5 mCi)
  - Resistance was noted during the administration and a high volume of saline was observed entering the vent vial
  - Residual microspheres in the delivery kit were higher than expected
  - Root cause was determined to be clumping of microspheres in the catheter
  - Corrective actions included exploration of ways to prevent catheter kinking with all AUs and review of all catheters in use to make sure they meet vendor requirements

35.1000 TheraSphere™

- Patient Underdose [250131]
  - Patient prescribed 380 MBq (10.27 mCi), received 130 MBq (3.51 mCi)
  - Root cause was determined to be malfunction of the delivery kit
  - Patient's treatment response will be closely monitored
  - Kit was retrieved by the manufacturer for investigation

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- Patient Underdose [250082]
  - Patient prescribed 1.84 GBq (49.73 mCi) and 0.8 GBq (21.62 mCi), received 1.075 GBq (29.05 mCi) and 0.549 GBq (14.84 mCi)
  - Manufacturer representative was present at this administration
  - AU set up treatment using radial access and the catheter provided was too short to gain access
  - The representative advised the AU placing the microcatheter into the holder on the steel arm extension and sliding the catheter hub into the holder was unnecessary, contradicting one of the steps in the administration checklist

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- Patient Underdose [250082] (cont.)
  - Post treatment analysis determined that not utilizing the extension arm and not lowering the patient bed eliminated the gravity-assist transition required when microspheres move from large to small diameter tubing, leading to microspheres being held up in the hub
  - Root cause was determined to be failure to follow manufacturer's instructions
  - Corrective actions included procedure updates and personnel retraining

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- Patient Underdose [250077]
  - Patient prescribed 4.13 GBq (111.62 mCi), received 1.88 GBq (50.81 mCi)
  - Manufacturer representative was present at this administration
  - AU set up treatment using radial access and the catheter provided was too short to gain access
  - The representative advised the AU placing the microcatheter into the holder on the steel arm extension and sliding teh catheter hub into the holder was unnecessary, contradicting one of the steps in the administration checklist

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- Patient Underdose [250077] (cont.)
  - Post treatment analysis determined that not utilizing the extension arm and not lowering the patient bed eliminated the gravity-assist transition required when microspheres move from large to small diameter tubing, leading to microspheres being held up in the hub
  - Root cause was determined to be failure to follow manufacturer's instructions
  - No adverse effects were expected
  - Corrective actions included procedures updates and personnel retraining

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- Patient Underdose [250069]
  - Patient prescribed 1.74 GBq (47 mCi), received 1 GBq (27 mCi).
  - Patient A mistakenly received the dose intended for patient B
  - Error was caught before patient B was treated
  - Root cause was determined to be human error; the vial lot numbers were transposed when entering them into the licensee's patient tracking system
  - Corrective actions included procedure modification
  - No adverse effects were expected and patient A returned for additional treatment

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- Patient Underdose [250055]
  - Patient prescribed 2.82 GBq (76.27 mCi), received 1.12 GBq (30.31 mCi)
  - AU used a smaller than recommended catheter during the administration due to patient anatomy
  - AU immediately felt resistance during the first flush and noticed that the overflow vial was full and overflowing
  - Additionally, the dosimeter monitoring the vial dropped to 0
  - The physician noted that no additional dosing was required
  - Root cause was determined to be use of a catheter that was too small with possible complications from a small dent in the tubing
  - Corrective actions included updating procedure checklist to inspect the tubing before use

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- Patient Underdose [240446]
  - Patient prescribed 1.82 GBq (49.2 mCi), received 1.24 GBq (33.6 mCi)
  - Administration proceeded as expected, no unusual pressures or leaks were observed and the dosimeter responded as expected
  - Additionally, the procedure steps were read out loud and verbally confirmed once each step was completed
  - Post-treatment surveys revealed activity at the hub of the delivery kit
  - Root cause was not able to be determined
  - Following decay, the delivery kit will be sent to the manufacturer for analysis

35.1000 TheraSphere™

- Patient Underdose [240382]
  - Patient prescribed 2.47 GBq (66.67 mCi), received 745.18 MBq (20.14 mCi)
  - Administering physician noted increased resistance during administration with filling of the overflow vial
  - Post-treatment investigation found spheres held up in the dose vial and the Leur lock
  - Root cause was determined to be an overtightening of the Leur lock, restricting flow
  - Corrective actions included checklist changes to include a reminder not to overtighten the lock

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- Patient Underdose [240377]
  - Patient prescribed 591.1 MBq (15.975 mCi), received 193.29 MBq (5.22 mCi)
  - Setup for the administration was completed with no issues and the first saline flush was completed successfully
  - Once the treatment started, the overflow vial began to fill and the dosimeter did not decrease
  - A cluster of microspheres were observed in the outlet tubing and actions were taken to break up this clump
  - Treatment continued but the microspheres still did not flow into the patient

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- Patient Underdose [240377] (cont.)
  - Following treatment, the catheter was confirmed to be correctly positioned and no kinks in the tubing were observed
  - Root cause was determined to be an occlusion of spheres in the treatment tubing for an unknown reason
  - Patient returned the next day to complete treatment

35.1000 SIR-Spheres®

- Patient Underdose [250370]
  - 5 Patients prescribed 1.44 GBq (38.92 mCi), 1.09 GBq (29.46 mCi), 1.08 GBq (29.19 mCi), 1.1 GBq (29.73 mCi), and 1.09 GBq (29.46 mCi)
  - All patients instead received 0.63 GBq (17.03 mCi)
  - Root cause was determined to be an internal licensee software issue with converting from GBq to mCi
  - Each patient was followed up on to ensure no adverse effects
  - Corrective actions included software fixes, personnel training on the new spreadsheet, and acquisition of new WD planning software

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- Patient Underdose [250151]
  - Patient prescribed 1.3 GBq (35 mCi), received 0.45 GBq (12.15 mCi)
  - During treatment the spheres became obstructed in the tubing and were unable to be cleared
  - Root cause was determined to be residual particles of gelfoam (an embolization material) in the tubing leading to microsphere accumulation
  - Saline flushes removed a small amount of the gelfoam before treatment but possible backflow of the spheres required the treatment to be halted
  - The patient was rescheduled for retreatment
  - Corrective actions included replacing the microcatheter after gelfoam embolization and prior to microsphere adminsitration

35.1000 SIR-Spheres®

- Patient Underdose [250139]
  - Patient prescribed 4 GBq (108 mCi), received 2 GBq (53.7 mCi)
  - Root cause was determined to be a kinked or clogged catheter
  - Corrective actions included retraining of personnel

35.1000 SIR-Spheres®

- Patient Underdose [250116]
  - Patient prescribed 0.5 GBq (108 mCi), received 0.4 GBq (10.81 mCi)
  - Event was discovered after a review of records two weeks post treatment due to a miscalculation of delivered activity
  - Procedure was stated to have been completed with no incident but there was more resistance during administration than usual
  - Root cause was determined to be either patient anatomy or the use of a small catheter
  - Patient was notified once the event was discovered
  - Corrective actions included reminders to recheck all calculations and development of an excel spreadsheet to assist in calculations

35.1000 SIR-Spheres®

- Patient Underdose [250039]
  - Patient prescribed 699.3 MBq (18.9 mCi), received 551.3 MBq (14.9 mCi)
  - No emergent patient conditions, shunting, or other blockages occurred during treatment
  - Additionally, the AU did not notice any unusual pressure or stasis
  - Root cause was determined to be a high concentration activity vial and a low prescription activity
  - Corrective actions included procedure updates

35.1000 SIR-Spheres®

- Patient Underdose [240388]
  - Patient prescribed 1.85 GBq (50 mCi), received 1.11 GBq (30 mCi)
  - During administration, the microcatheter became blocked and the procedure was stopped
  - Root cause was determined to be restriction of flow due to closing of the microcatheter due to bends in the patient's anatomy
  - AU believed that the dose delivered was therapeutic and did not expect any adverse effects
  - Corrective actions included discontinuing use of that make and model of microcatheter

Summary

- 35.200
  - Single event due to human error in ordering doses
  - Shows importance of communication and crosscheck for all doses, not just therapy
  - Electronic tracking systems were suggested to be implemented in IN-2026-02 “Using Generic Process Checklists in Medical Care to Prevent Human Error”

Summary

- 35.300
  - Human error consistently shows up in root causes; distractions leading to overdoses, incorrect calculations on paper, lack of WD reviews
  - Equipment failures were also high this year, primarily with the use of stopcocks and delivery systems
  - Some root causes were difficult to determine or occurred even when all procedures were followed
  - Issues explored in IN-2024-04 “Recent Medical Events Involving Administrative of Therapeutic Radiopharmaceuticals” and IN-2026-02 “Using Generic Process Checklists in Medical Care to Prevent Human Error”

Summary

- 35.600
  - Human error caused the majority of HDR events this year
  - Continue to have issues with determining the correct site to treat
    - Verify treatment sites on WD and when multiple medical team members are on the case
  - Incorrect catheter lengths leading to an underdose
  - Shifting catheter during treatment

Summary

- 35.1000
  - Only Underdoses this year (1 GSR, 26 microspheres)
  - Equipment issues for the GSR, error state completed successfully
  - Similar issues to previous years (small catheter use, high activity concentration vials, patient conditions)
  - New places for equipment failure (use of gelfoam)
  - Errors associated with dose decay, ordering, and activity calculations
    - Might be prevented with use of techniques in IN-2026-02
  - First Eye90 microspheres® event

Summary

- Non-Medical Events of Interest
  - Extravasation/infiltration events continue to be non-reportable under NRC regulations
    - Small number of events with no harm to the patient
  - Incident involving a new physician that was in the process of, but not finished with, becoming an AU
    - Reviewed by an AU with no harm to the patient
    - Physician has since been approved
  - One incident involving a mistake in infusing amino acids prior to a Lu-177 injection
  - Some events were redacted because recalculations of dose delivered moved them out of the 20% threshold

Acronyms

- AU – Authorized User
- FY – Fiscal Year
- GSR- Gamma Stereotactic Radiosurgery
- HDR – High Dose Rate Remote Afterloader
- IR – Interventional Radiology
- NMT – Nuclear Medicine Technologist
- RO – Radiation Oncologist
- RSO – Radiation Safety Officer
- WD - Written Directive



Questions?