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

Status of Medical Events FY 2024

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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 2019 - 2024

	FY19	FY20	FY21	FY22	FY23	FY24
35.200	1 (8*)	0	4	0	1	0
35.300	9	2	10	10	11	7
35.400	5	6	4	1	3	1
35.600	9 (10*)	13	5	11 (40*)	8	6
35.1000	32	27	41	34	36	34
Total	56	48	64	56	59	48

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

Medical Events 2024

35.300 Medical events	**7**
Ra-223	2
Lutetium-177	3
I-131	2

35.300 Ra-223

- Patient Underdose [240289]
  - Prescribed 3.3 MBq (89.2 µCi), administered 1.68 MBQ (45.53 µCi)
  - Medical physicist deviated from written directive procedure to measure the activity in the dose calibrator and then deliver the dose
  - MP delivered the dose after adjusting using an outdated and incorrect formula
  - State initiated an investigation

35.300 Ra-223

- Patient Underdose [240289]
  - Prescribed 3.37 MBq (91.2 µCi), administered 2.68 MBq (72.46 µCi)
  - Medical physicist deviated from written directive procedure to measure the activity in the dose calibrator and then deliver the dose
  - MP delivered the dose after adjusting using an outdated and incorrect formula
  - State initiated an investigation
  - Same patient as previous event (2 doses with 2 separate WDs one month apart)

35.300 Lu-177

- Patient Overdose [240075]
  - Patient prescribed 3.7 GBq (100 mCi), received 7.4 GBq (200mCi)
  - Original WD called for 7.4 GBq but oncologist had signed a dose alteration plan for 3.7 GBq
  - Alteration was not captured in the WD modification, and the full dose was delivered
  - Multiple root causes were identified, including changes in dose not being seen, not all employees having access to the patient electronic medical records, unavailability of reduced dosage ordering and a lack of dual sign off by Infusion Nurse and Nuclear Medicine staff
  - No adverse effects are expected
  - Corrective actions included WD completion closer to the actual therapy, creation of a reduced dose order in electronic records, inclusion of dual verification of dose, and discussion of reduced dose directly with the AU

35.300 Lu-177

- Patient Overdose [230483]
  - Patient prescribed 5.55 GBq (150 mCi), received 7.4 GBq (200 mCi)
  - Patient was unintentionally administered the full dose, rather than the reduced dose
  - Root cause was determined to be lack of WD review and lack of timeout use before the procedure
  - No adverse effects are expected
  - Corrective actions included a review of the WD format and improvement of the two-technologist pre-treatment timeout procedure
  - Additional actions included reeducation stressing the importance of the pre-treatment timeout and attention to detail

35.300 Lu-177

- Patient Underdose [240041]
  - Prescribed 7.4 GBq (200 mCi), administered 5.54 GBq (149.7 mCi)
  - Treatment went as planned; a survey meter positioned to monitor the vial determined that activity had been delivered to the patient
  - Post-treatment survey noted a residual activity of 1.62 GBq (43.7 mCi)
  - Investigation determined that due to changes in the licensee supply chain, a new IV set was being used
  - This new set did not have a clip to prevent backflow into the pump, which resulted in a visual constriction of the IV line
  - Technologist attempted to open up the tubing, which seemed successful after manipulation
  - Corrective actions included changing the procedure for infusion and repositioning the survey meter to more directly measure the activity in the vial

35.300 I-131

- Patient Overdose [230491]
  - Patient prescribed 3.7 GBq (100 mCi), received 5.92 GBq (160 mCi)
  - Root cause was determined to be human error
  - NMT misinterpreted sloppy handwriting by the AU on the WD and the AU failed to confirm the dose during the pre-treatment phase of the administration
  - Additionally, more minor discrepancies on the WD indicated a lack of oversight by the RSO
  - Adverse effects included an increased cancer risk due to an additional whole body dose of approx. 62 rem
  - Corrective actions included procedure updates for WD (including typing of prescribed dose), additional training for Aus on WDs, and more frequent RSO audits of WDs

35.300 I-131

- Patient Underdose [240143]
  - Prescribed 3.7 GBq (100 mCi), administered 0.148 GBq (4 mCi)
  - When performing routine radiation surveys at the end of the day the licensee found the 3.7 GBq capsule in its original packaging
  - Determined that the patient had only been given the diagnostic capsule
  - Root cause was determined to be a lack of dose confirmation on the written directive prior to administration
  - Corrective actions included education of NMTs on proper patient and activity processing
  - Additionally, procedures were revised to provide clarity on NMT responsibilities

Medical Events 2024

35.400 Medical events	**1**
Cs-131 (GammaTile)	1

35.400 GammaTile

- Patient Underdose [240198]
  - Prescribed 6,000 cGy (rad), received 3,600 cGy (rad)
  - 40 seeds successfully implanted in the brain for treatment
  - Patient returned due to medical complications and had the seeds removed over two procedures
  - Seven seeds were lost post-explantation, state conducted an on-site investigation
  - Corrective actions included additional training for neurosurgery staff

Medical Events 2024

35.600 Medical events	**6**
HDR	6

35.600 HDR

- Patient Overdose [230454]
  - 218.49 GBq (5.905 Ci) Ir-192 HDR unit
  - Prescribed 3,400 cGy (rad) over 10 fractions, received 4,420 cGy (rad)
  - Dwell times were not verified between planning and delivery systems for 8 fractions before being identified
  - Delivery system was on a Windows XP based personal computer that could not be on the licensee network due to security reasons
  - This configuration prevented communication between the planning and delivery systems, resulting in incorrect dwell times
  - No effects were noted to the patient, treatment was considered completed

35.600 HDR

- Patient Overdose [230436]
  - Expected dose to non-target organ was 200 cGy (rad), delivered 340 cGy (rad)
  - First fraction of treatment was delivered for management of cervical cancer when the error occurred
  - Follow-up determined that HDR channel assignments had been reassigned during setup mistakenly, followed by a failure to confirm proper channel assignment during the pre-procedure timeout

35.600 HDR

- Patient Overdose [230436] (cont.)
  - Patient proceeded with the rest of the treatment successfully, with no additional effects from the overdose
  - Corrective actions included retraining HDR staff on applicator configuration and verification of channel connection
  - Additionally, the licensee considered the use of different lengths of transfer tubes for different channels to physically distinguish it from other channels

35.600 HDR

- Patient Overdose [230517]
  - Patient was prescribed 236.8 cGy (rad), received 362 cGy (rad)
  - Patient was scheduled to receive treatment but was mistakenly administered the first fraction of a previous patient's treatment
  - Physicist set up the new patient in the HDR vault and confirmed that the patient was correct, without closing the previous treatment plan
  - Physicist closed the previous treatment plan after exiting the vault
  - Physicist then inadvertently re-opened the previous treatment plan and delivered the first fraction to the wrong patient

35.600 HDR

- Patient Overdose [230517] (cont.)
  - Physicist caught the error once they tried to upload the post-treatment summary and noticed there was one already completed
  - Dose evaluation was completed, and the remaining 9 fractions were changed to compensate for the overdose, resulting in a final dose only 2% below the original treatment plan
  - Corrective actions included modifications to the patient check in procedure, additional sign offs on the console treatment plans, and another verification to ensure the computer treatment plan and the prescribing computer plan match regarding the active patient

35.600 HDR

- Wrong Site [230461]
  - Patient prescribed three treatments of 550 cGy, total of 1,650 cGy (rad) to the uterus
  - During the third fraction, treatment was interrupted due to fluid in the transfer tubing
  - Replacement tubing was not the correct length, resulting in the source being outside of the patient for 10 seconds
  - Localized skin dose to the patient's thigh was estimated to be 300 cGy (rad) in a worst-case, direct contact scenario and 50 cGy (rad) for a more realistic, 8mm distance scenario
  - Physician noted that the dose was below the level likely to cause injury

35.600 HDR

- Wrong Site [230461] (cont.)
  - Delivered dose during this fraction was within 20% of the expected dose to the uterus
  - Corrective actions included leak testing tubing and revision of procedures to verify tubing length before starting treatment
  - Additionally, new procedures were developed for interruption of treatment to adjust patient setup

35.600 HDR

- Patient Underdose [240081]
  - 438.82 GBq (11.86 Ci) I-192 HDR Unit
  - Prescribed 600 cGy (rad) fractions, received 100 cGy (rad) for the third treatment
  - Dwell positions with two ovoid applicators was successful, but was obstructed with the tandem applicator
  - Repeated checks and attempts were unsuccessful, leading to the underdose
  - Investigation of the applicator found microfractures in the tandem
  - Licensee noted the matter seemed to be related to the autoclaving process for the applicators
  - Corrective actions included applicator replacement and development of additional precautionary safety procedures
  - Patient treatment was revised and successfully completed

35.600 HDR

- Patient Underdose [240044]
  - 236.06 GBq (6.38 Ci) Ir-192 HDR unit
  - Patient prescribed 550 cGy (rad) per fraction, received 60.5 cGy (rad)
  - Treatment time was determined to be six minutes and 15 seconds over nine dwell positions
  - After starting treatment, timer froze at six minute and seven seconds
  - Physician stopped the treatment once the freeze was noticed, estimating the treatment time to be around 30-40 seconds
  - Investigation found that the device was functioning normally, and the timer freeze was unable to be replicated or verified
  - Licensee paused their HDR program until more troubleshooting could be performed

Medical Events 2024

35.1000 Medical events	**34**
GSR	1
Y-90 Microspheres	
– Unknown	3
– TheraSphere™	27
– SIR-Spheres®	3

35.1000 Gamma Stereotactic Radiosurgery

- Wrong Site [240018]
  - Patient was prescribed 80 Gy (8000 rad) to the left trigeminal nerve, delivered full dose to the right trigeminal nerve
  - MP misidentified the nerves during pre-treatment and the reviewing neurosurgeon and oncologist did not notice the error during the plan review
  - No adverse effects are expected
  - Corrective actions included implementation of new procedures for GSR procedures, additional peer reviews by a gamma knife trained oncologist, and a verbal timeout before all cases.
  - The state conducted a follow-up investigation and had no adverse findings from the inspection, closing the investigation

35.1000 Y-90 Microspheres

- Patient Overdose [240113]
  - Patient prescribed 2.6 GBq (70 mCi), delivered 3.13 GBq (84.5 mCi)
  - Technologist drew up 3.17 GBq (85.8 mCi)
  - Treatment was delivered within 30 minutes of the dose being drawn
  - Incident was discovered during a quarterly review a month later
  - Both AU and patient referring physician were satisfied with the activity delivered

35.1000 Y-90 Microspheres

- Patient Underdose [240351]
  - Prescribed 14,700 cGy (rad), received 5,880 cGy (rad)
  - Licensee suspected stasis

35.1000 Y-90 Microspheres

- Patient Underdose [240092]
  - Patient received 30% of prescribed dose
  - When inserting the catheter, vein contusions caused the underdose to occur
  - Licensee noted the incident did not cause stasis

35.1000 TheraSphere™

- Wrong Site [240352]
  - Patient prescribed 2.18 GBq (59 mCi), received 0.970 GBq (25 mCi)
  - During administration some of the dose as deposited in the stomach, resulting in a dose of 99 Gy (9,900 rad)
  - Root cause was determined to be a blockage and subsequent rupture of the catheter, noting that the administering physician felt resistance during administration
  - Licensee also noted that they were using a manufacturer recommended catheter and followed administration protocol

35.1000 TheraSphere™

- Wrong Site [240352] (cont.)
  - Corrective actions included advising IR AUs of this issue at conferences, notifying the vendor of the event, and notifying the licensee department of quality and safety
  - Treatment was paused to determine the extent of adverse effects
  - No symptoms were noted and the state confirmed that all recommendations were followed for the event

35.1000 TheraSphere™

- Wrong Site [240321]
  - Patient prescribed 1.31 GBq (45.92 mCi) for a dose of 250 Gy, mistakenly delivered 97 Gy (9,700 rad) to the stomach
  - Root cause was human error, the team did not do a pretreatment mapping study before delivery
  - Severe adverse effects are expected
  - Corrective actions included education of all IRs, and a new, formal process for the treatment team to review correct MAA and angiography mapping techniques
  - State investigation is ongoing, expecting escalated enforcement actions

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- Wrong Site [240272]
  - Patient prescribed 0.77 GBq (20.81 mCi), received 0 GBq (0 mCi)
  - All dose was deposited to stomach for a dose of 19,880 cGy (rad)
  - All recommended pre-treatment imaging was performed, including an angiogram the day of the treatment, showing no stomach filling
  - Post-treatment imaging revealed that the full dose had been deposited in the stomach

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- Wrong Site [240272] (cont.)
  - Root cause was not able to be definitively determined but the licensee believes that atypical flow was misinterpreted during pre-treatment planning
  - Additionally, 1 month before the treatment the patient was undergoing immunotherapy and angiogenesis treatment, which may have contributed to the event
  - Patient was treated for adverse effects to the GI system and appears to be recovering
  - Corrective actions included guidance for mapping studies with regards to abnormal arterial structure, use of cone beam CT to augment the pretreatment studies, and clear instructions to staff about reporting requirements

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- Wrong Site [240183]
  - Patient prescribed 0.613 GBq (16.57 mCi), received 0.582 GBq (15.73 mCi) to treatment site
  - Post-treatment analysis revealed and uptake to the stomach of 1,400 to 2,000 cGy (rad)
  - Follow-up with the patient showed no complications to the GI system
  - Root cause was suspected to be complex vascularity of the tumor not identified by two MAA mapping studies
  - The licensee stated that since the second MAA mapping was done the day of the treatment it was possible the MAA particles may have partially altered the flow dynamics of the tumor
  - No corrective actions were taken given that the administration had been given according to manufacturer's recommendation

35.1000 TheraSphere™

- Patient Underdose [240114]
  - Patient prescribed 1.79 GBq (48.38 mCi), delivered 0.67 GBq (18.11 mCi)
  - Root cause was determined to be the unintentional use of a smaller catheter than recommended by the manufacturer (0.019” inner diameter instead of 0.02”)
  - No adverse effects were expected and the dose delivered was determined to be clinically effective
  - Corrective actions included additional training on verification of catheter size for IR technologists and AUs, and revision of the SOP to include a step for catheter size verification

35.1000 TheraSphere™

- Patient Underdose [240305]
  - Patient prescribed 1.2 GBq (32.44 mCi), received 0.82 GBq (22.26 mCi)
  - Root cause was determined to be a kink in the catheter
  - Corrective actions included reminders to check flow through the microcatheter prior to administration and to keep watch on the overflow vial during the administration

35.1000 TheraSphere™

- Patient Underdose [240299]
  - Patient prescribed 2.072 GBq (56 mCi), received 1.369 GBq (36.95 mCi)
  - Treatment was intended to be two doses (A and B) for separate sections of the liver
  - Dose for segment B was mistakenly delivered to segment A
  - Incident was immediately discovered before delivering dose to segment B

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- Patient Underdose [240238]
  - Patient prescribed 4.29 GBq (116 mCi), received 0.1 GBq (2.62 mCi)
  - During treatment a tubing failure led to the suspension of treatment
  - Patient was rescheduled for treatment
  - Kit was held for decay to send to the manufacturer for analysis

35.1000 TheraSphere™

- Patient Underdose [240229]
  - Patient prescribed 3.712 GBq (100.32 mCi), received 0.3 GBq (8.1 mCi)
  - Attending physician noted no unusual signs during treatment
  - Inspection found that written procedures were not implemented to provide high confidence that the administration was performed in accordance with the written directive
  - A catheter smaller than recommended was used, individuals working under the supervision of the AU were not properly trained, and the AU was not physically present during the treatment
  - Corrective actions included procedural changes to include catheter planning multiple times during the process

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- Patient Underdose [240208]
  - Patient prescribed 29,300 cGy (rad), 9,500 cGy (rad)
  - Patient was prescribed two administrations of microspheres, first vial was the underdose, second was uneventful
  - Event was discovered when surveying the waste post-treatment
  - Root cause was determined to be momentary stoppage of microsphere flow due to actuation of the relief valve, leading to microspheres dropping out of suspension
  - Patient was scheduled for additional treatment
  - No corrective actions were taken

35.1000 TheraSphere™

- Patient Underdose [240184]
  - Patient prescribed 1.304 GBq (35.24 mCi), received 0.931 GBq (25.16 mCi)
  - Root causes were determined to be clumping of microspheres in the V-vial, occlusion of the needle puncturing the vial, or kinking of the microcatheter
  - Corrective actions included updating procedures to lift the vial and shield out of the kit and striking it to loosen any microspheres if dosimeter readings are elevated
  - Additionally, flushing will continue until dosimeter readings are at background

35.1000 TheraSphere™

- Patient Underdose [240168]
  - Patient prescribed 1.77 GBq (47.9 mCi), received 0.248 GBq (6.7 mCi)
  - Patient prescribed 2 treatments with 2 WDs, underdose occurred on the second
  - Administering physician noted resistance due to a kinked catheter during treatment
  - Root cause was determined to be a kinked catheter due to tortuous anatomy
  - Flushing the catheter did not alleviate the resistance but did result in minor contamination of the IR suite
  - Surveys and decontamination of the room occurred without incident or overexposure

35.1000 TheraSphere™

- Patient Underdose [240159]
  - Patient prescribed 1.347 GBq (36.4 mCi), received 1.029 GBq (27.8 mCi).
  - Root cause was determined to be use of a smaller than recommended catheter (Catana 2.5F), tenuous patient branch anatomy, and not replacing the microcatheter after performing the bland embolization
  - No adverse effects were expected, and retreatment was not deemed to be necessary

35.1000 TheraSphere™

- Patient Underdose [240155]
  - Patient prescribed 560 MBq (15.135 mCi), received 49.99 MBq (1.351 mCi)
  - Root cause was determined to be clumping of microspheres due to overtightening of the Tuohy Leur lock
  - Dose information was obtained from post-treatment analysis of the waste
  - No negative health effects were expected, and the treatment was rescheduled

35.1000 TheraSphere™

- Patient Underdose [240135]
  - Patient prescribed 2.11 GBq (57.03 mCi), received 0.477 MBq (12.9 mCi)
  - No adverse effects are expected
  - State performed an on-site inspection
  - Root cause was determined to be blockage of the administration line because of a faulty needle in the plunger of the administration kit

35.1000 TheraSphere™

- Patient Underdose [240053]
  - Patient prescribed 1.29 GBq (34.99 mCi), received 0.853 GBq (23.05 mCi)
  - The administering physician noted significant resistance during treatment and on saline flushes
  - Root cause was determined to be clumping of the microspheres with the reason being unclear
  - No adverse effects are expected and the physician determined that the patient did not need to be retreated

35.1000 TheraSphere™

- Patient Underdose [240048]
  - Patient prescribed 380 MBq (10.27 mCi), received 160 MBq (4.32 mCi)
  - Root cause was determined to be an obstruction in the microcatheter
  - No adverse effects were expected, and retreatment plans are being evaluated
  - No shunting was noted during the treatment
  - Waste was delivered to the manufacturer for further investigation

35.1000 TheraSphere™

- Patient Underdose [240032]
  - Patient prescribed 489.6 Gy (rad), received 113.9 Gy (rad)
  - Root cause was determined to be blockage of the catheter due to unadministered microspheres
  - Retreatment was planned
  - Corrective actions included procedure changes

35.1000 TheraSphere™

- Patient Underdose [240013]
  - Patient prescribed 3.5 GBq (94.59 mCi), received nearly 0 GBq
  - During the second of two administrations post-treatment surveys indicated nearly all of the dose remained in the delivery tubing
  - Patient was planned to be retreated in the future
  - State performed a reactive inspection
  - Investigation determined the root cause to be clumping of the microspheres with time between dose preparation and delivery being a possible complicating factor

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- Patient Underdose [240009]
  - Patient prescribed 10,500 cGy (rad), received 5,050 cGy (rad)
  - Tubing failure resulted in microspheres being contained in the device tubing
  - No spill occurred and the manufacturer representative observed the event
  - Remainder of the prescribed dose was scheduled to be delivered at a later date
  - Corrective actions included procedural changes for a more thorough inspection of device tubing and to agitate the vial prior to administration

35.1000 TheraSphere™

- Patient Underdose [230509]
  - Patient prescribed 1.86 GBq (50.27 mCi), received 1.019 GBq (27.54 mCi)
  - All pre-treatment procedures were completed but MAA showed possible reflux to the bowel
  - Physician cautiously delivered the dose, and when removing the catheter, the survey equipment showed a higher than usual level of background radiation
  - Post-treatment survey showed activity in the delivery system
  - Root cause was determined to be reflux issues causing activity to remain in the kit, and the physician not risking bowel reflux with additional flushes
  - Corrective actions included patient monitoring for reflux and anatomical issues, and ensuring that all additional flushes will be completed

35.1000 TheraSphere™

- Patient Underdose [230480]
  - Patient prescribed 1.51 GBq (40.89 mCi), received 0.84 GBq (22.59 mCi)
  - Treatment was administered with no complications and three saline flushes were completed
  - Post-treatment surveys indicated residual activity in waste
  - Investigation showed a rupture in the microcatheter passing through the Y-fitting, allowing microspheres to collect in the fitting
  - No adverse effects to the patient were expected
  - Corrective actions included manufacturer communication and refresher training to the staff on set-up of administration lines

35.1000 TheraSphere™

- Patient Underdose [230471]
  - Patient prescribed 976 MBq (26.38 mCi), received 96 MBq (2.59 mCi)
  - Pre-treatment flush of the catheter with saline and contrast solution was uneventful but attempts to deliver the microspheres were unsuccessful
  - Root cause was determined to be a kink in the catheter due to tortuous anatomy, possibly because of the difference in pressure between the flushes (200 psi) and the microspheres (30 psi)
  - No adverse effects were expected
  - Corrective actions included education about this issue for other AUs

35.1000 TheraSphere™

- Patient Underdose [230469]
  - Patient prescribed 11,800 cGy (rad), received 6,431 cGy (rad)
  - Treatment involved three vials, 1 occurred without incident but the physician noted increased resistance delivering 2 and 3
  - Root cause was determined to be user error
  - Mandrel was not removed before attempting to remove the microcatheter from the packaging, causing internal damage affecting the yield in vial 1 and 3
  - No adverse effects were expected but the patient was followed for possible retreatment
  - Corrective actions included sharing awareness of proper unpackaging technique, additional monitoring by the AU, and generic discussion on IR tasks was held among the operational leadership

35.1000 TheraSphere™

- Patient Underdose [230464]
  - Patient prescribed 12,000 cGy (rad), received 4,170 cGy (rad)
  - During line check while attempting to administer the microspheres, the administering physician experienced some difficulties, stopped the procedure, and noticed a higher than usual background reading
  - Imaging of the patient revealed very little of the dose was delivered
  - No adverse effects were expected but the patient was monitored for the next two weeks
  - The licensee planned to hold the kit for decay and send it to the manufacturer for analysis
  - Corrective actions included procedure revision

35.1000 TheraSphere™

- Patient Underdose [230434]
  - Patient prescribed 562.4 MBq (15.2 mCi), received 399.97 MBq (10.81 mCi)
  - AU noticed high back pressure during the treatment
  - Possible root causes were stated to be issues with the administration set or coring of the septum but no definitive cause was identified
  - No adverse effects were expected and the dose was determined to be clinically effective
  - No corrective actions were taken since there was no clear root cause and no violations were identified during the investigation

35.1000 TheraSphere™

- Patient Underdose [230432]
  - Patient prescribed 266.4 MBq (7.2 mCi), received 207.72 MBq (5.614 mCi)
  - Root cause was determined to be microspheres held up in the hub due to inadequate flush volume
  - No adverse effects are expected, and no additional treatment was needed
  - Corrective actions included education with a follow-up safety committee meeting, and flushing of microspheres with 30 cc of fluid, barring stasis

35.1000 SIR-Spheres®

- Patient Overdose [240333]
  - Patient prescribed 199.8 MBq (5.4 mCi), received 253.08 MBq (6.84 mCi)
  - Incident discovered during a quarterly records review
  - Root cause was determined to be the small activity of the dose, personnel had difficulty drawing microspheres into the syringe without under or overdosing the vial
    - The licensee noted that treatments under 370 MBq (10 mCi) generally have a 15% residual activity
  - No adverse effects to the patient were expected and the dose delivered was considered clinically acceptable

35.1000 SIR-Spheres®

- Patient Underdose [230155]
  - Patient prescribed 499.5 MBq (13.5 mCi), received 295.63 MBq (7.99 mCi)
  - Treatment was suspended due to tubing failure
  - Patient was rescheduled for follow-up treatment
  - Investigation could not find the cause of the clogged tubing and both the manufacturer and the licensee noted that the tubing size was acceptable for the procedure

35.1000 SIR-Spheres®

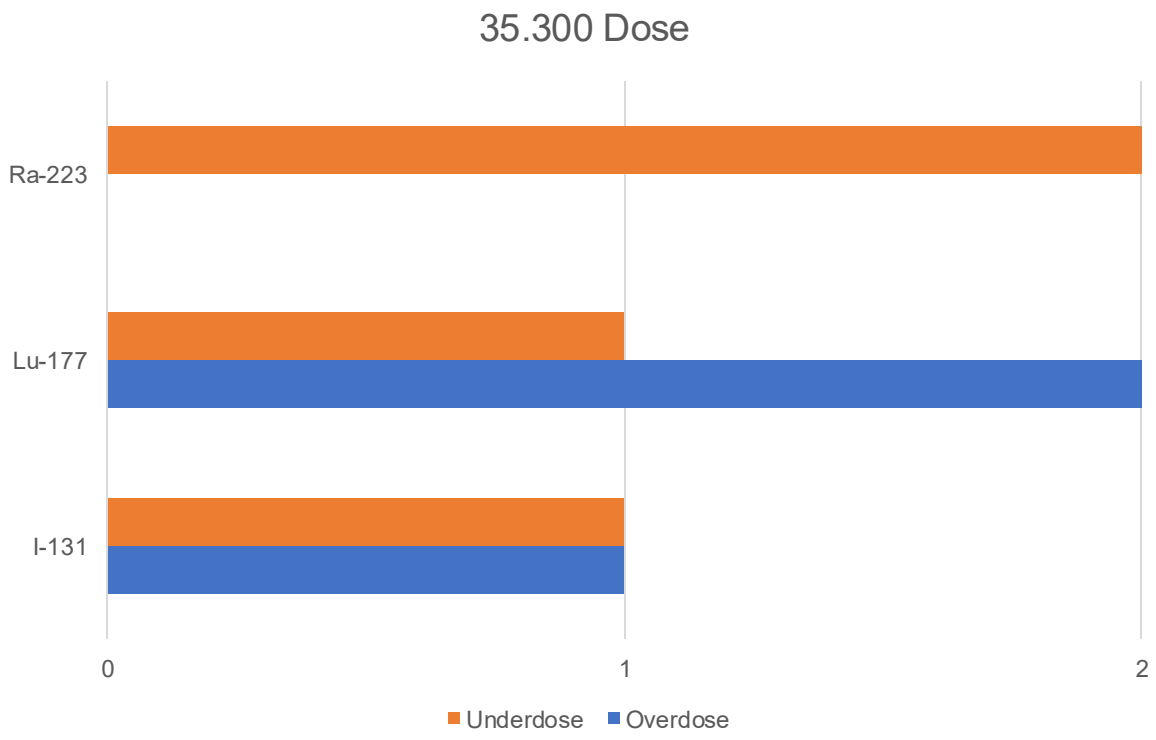
- Patient Underdose [240274]
  - Patient prescribed 708.18 MBq (19.14 mCi), received 285.64 MBq (7.72 mCi)
  - During the treatment a leak was discovered in the system tubing and treatment was stopped
  - Connection was reestablished and treatment continued, after which all contamination was remediated
  - Root cause was determined to be the treating physician's error to properly connect the tubing to the microcatheter
  - No adverse effects were expected and the dose delivered was considered therapeutically adequate
  - Corrective actions included double checks of all tubing and injecting contrast to check for leaks before administration

Summary

- 35.300
  - Ra-223 underdoses both resulted from the use of a dose administration equation from an outdated manufacturer document
  - Shows importance of using current manufacturer recommendations and regularly updating procedures based on these recommendations
  - Lu-177 overdoses resulted from administration of full doses instead of reduced doses
  - Lu-177 underdose resulted from supply chain issues and loss of expected equipment

Summary

- 35.300 (cont.)
  - Iodine underdose due to human error, no confirmation of dose delivery
  - Many of these issues are explored in IN-2024-04

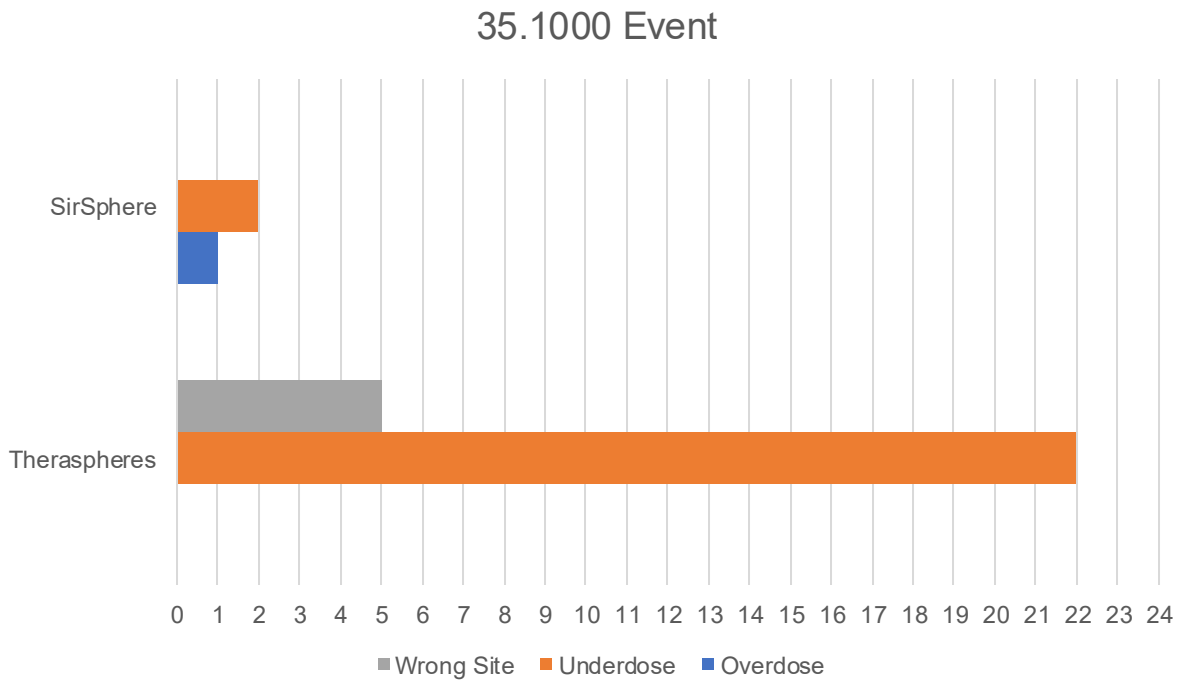


Summary

- 35.600
  - No identifiable trend or connecting thread for events this year
  - Human error dominates the root causes, mostly through improper use of equipment or use of improper equipment
  - Verification of proper and intact equipment
  - Verification of treatment parameters and patient treatment plan

Summary

- 35.1000
  - GI deposition events
  - Issues with correct equipment usage (catheters and tubing)
  - Clumping of microspheres due to a variety of issues including time between administration and dose prep, low pressure during administration, and use of improper equipment.



Acronyms

- AMP – authorized medical physicist
- AU – Authorized User
- Cs-131 – Cesium-131
- FY – Fiscal Year
- HDR – High Dose Rate Remote Afterloader
- I-192 –Iridium-192
- IVB – Intravascular Brachytherapy
- IR – Interventional Radiology
- Lu-177 – Lutetium-177

Acronyms

- NMT – Nuclear medicine technician
- RSO – radiation safety officer
- WD - Written Directive
- Y-90 – Yttrium-90

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QUESTIONS?