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

Status of Medical Events FY 2022

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Medical Events

The dose threshold for diagnostic events precludes reportable events most years.

Each year, there are approximately 150,000 therapeutic procedures performed utilizing radioactive materials.

Medical Events FY 2017 - 2022

	FY17	FY18	FY19	FY20	FY21	FY22
35.200	0	0	1 (8*)	0	4	0
35.300	4	2	9	2	10	10
35.400	7	11 (13*)	5	6	4	1
35.600	8 (14*)	10	9 (10*)	13	5	11 (40*)
35.1000	24	25 (26*)	32	27	41	34
Total	43	48	56	48	64	56

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

Medical Events 2022

35.200 Medical events	**0**

Medical Events 2022

35.300 Medical events	**10**
Lutetium-177	4
I-131 NaI	3
Ra-233	2
Ac-225	1

35.300 I-131 NaI

- Patient overdose [210490]
  - Patient prescribed 0.074 GBq (2mCi), received 5.62 GBq (152 mCi)
  - Patient intended to receive 5.55 GBq (150 mCi), signed in medical record
  - Error in computer-generated written directive
  - No harm because intended treatment was administered
  - Corrective actions included changes to computer-generated written directive and procedure changes to existing timeout process

35.300 I-131

- Patient underdose [210455]
  - Prescribed 3.7 GBq (100 mCi), administered 2.9 GBq (78.5 mCi)
  - Therapeutic portion of a sponsored study protocol
  - Fixed activity administration limited by kidney dose, no reliable dose estimate for the prostate
  - Root cause determined to be inadequate training on protocol
  - Corrective actions included additional training
  - No adverse impacts were expected
  - Follow-up doses were cancelled due to proximity to kidney dose constraints

35.300 I-131

- Patient underdose [210448]
  - Patient prescribed 925 MBq (25 mCi), received 370 kBq (10 μCi)
  - Administered I-131 capsule, was unable to swallow and pill broke down in mouth
  - Capsule was removed and taken to safe room
  - Some removed pharmaceutical leaked, leading to a contamination incident
  - Second administration of liquid I-131 attempted the next day, patient also failed to swallow
  - Dose from first administration estimated by bioassay
  - Corrective actions included having patients swallow a placebo pill prior to administration
  - No persons were determined to be contaminated; decontamination of surfaces was successful

35.300 Lu-177 Lutathera

- Patient overdose [220331]
  - Prescribed 3.7 GBq (100 mCi), administered 7.62 GBq (206 mCi)
  - Patient had kidney disease, requiring the smaller dosage
  - Administering tech did not receive the written directive from NM Dept
  - Pharmacy tech drew typical dosage of 7.4 GBq (200 mCi), did not consult written directive
  - Root cause was determined to be failure to follow established protocols and lack of communication within department
  - Corrective actions included a “daily huddle” to communicate key information about the day’s therapy patients
  - Additionally, the secondary verification now requires a physical signature on the written directive
  - Patient will be followed to assess for kidney damage

35.300 Lu-177 Lutathera

- Patient overdose [220328]
  - Prescribed 3.7 GBq (100 mCi), administered 7.62 GBq (206 mCi)
  - Third of four treatments, previous treatments also prescribed 3.7 GBq (100 mCi) due to reduced creatinine clearance
  - Delay in treatment due to suspension of radioisotope production
  - Resulted in adequate creatinine levels for the treatment, doses to non-target tissues was in line with parameters for a standard treatment
  - Final treatment was planned to be either a full or half dose, depending on patient tolerance
  - Written directive was updated to improve verification process of dose measurement

35.300 Lu-177 Lutathera

- Patient underdose [220128]
  - Patient prescribed 7.62 GBq (206 mCi), received 1.48 GBq (40 mCi)
  - Two minutes after infusion, leak was noticed in line
  - Procedure stopped and vial and tubing assayed
  - Wipe tests showed no patient contamination
  - Room was surveyed and appropriately decontaminated
  - Root cause was equipment failure, corrective actions were implemented
  - No clinical impact or risks to the patient

35.300 Lu-177

- Patient underdose [220114]
  - Patient prescribed 7.4 GBq (200 mCi), received 0.052 GBq (1.4 mCi)
  - Vial lost pressure during treatment
  - Remedial measures attempted but failed
  - No contamination found
  - No adverse effects noted

35.300 Ra-223

- Patient overdose [220338]
  - Patient prescribed 2.13 MBq (57.5 µCi), received 6.84 MBq (184.9 µCi)
  - Clerical error in written directive, patient received intended dose

35.300 Ra-223 Xofigo

- Patient underdose [220340]
  - Patient prescribed 7.83MBq (211.6 µCi), received 5.92 MBq (160 µCi)
  - Leakage occurred in three-way stopcock during administration
  - Administered dose estimated by measuring the leaked radiopharmaceutical
  - Root cause was determined to be incorrect cap used on the unused port
  - Corrective actions included procedure revisions to prevent leakage and additional training
  - No harm is expected to the patient

35.300 Ac-225

- Patient underdose [210503]
  - Patient prescribed 5.55 MBq (150 µCi), received 4.22 MBq (114 µCi)
  - Clinical trial for prostate cancer
  - Accidental discharge onto absorbent pad
  - Root cause determined to be the recession of the connection point into the tungsten shield, hindering operation of the three-way stopcock
  - AU removed connection without required three saline flushes
  - Corrective actions included retraining of all AUs, refresher training on written directives, and acquisition of an alpha detector to survey for contamination

Medical Events 2022

35.400 Medical events	**1**
Eye Plaque	1

35.400 I-125 Eye Plaque

- Patient underdose [210459]
  - Prescribed 8,500 cGy (rad), received 1,695 cGy (rad)
  - Plaque held 30 seeds with an activity of 49.21 MBq (1.33 mCi) in each seed
  - Plaque dislodged while patient rubbed eye
  - Plaque placed in lead pouch and returned to AU
  - No corrective actions taken

Medical Events 2021

35.600 Medical events	**11**
HDR	10
PDR	1

35.600 HDR

- Patient overdose [220167]
  - 333 GBq (9 Ci) I-192 HDR Unit
  - Prescribed 10 HDR treatments, following four treatments the licensee noticed some source catheters had been mislabeled
  - Planned skin dose was 26.5 Gy (2650 rad), after adjustments the dose to skin was 48.4 Gy (4840 rad)
  - No adverse effects expected but patient will have more frequent follow-up
  - Root cause determined to be human error and lack of proper catheter identification
  - Corrective actions included procedure updates to emphasize catheter identification and modification of planning process to include an additional review by a second physicist
  - Staff also received additional training

35.600 HDR

- Patient underdose [220186]
  - 370 GBq(10 Ci) Ir-192 HDR unit
  - 2 patients both prescribed 4 fractions of 7 Gy (700 rad) for a total of 28 Gy (2800 rad)
  - First patient had an underdose in fraction 2 of 4, only 79.1% of he fraction was delivered
  - Second patient had an underdose in fraction 4 of 4, only 54.4% of the fraction was delivered
    - Additionally, this patient received a 48% greater dose to the rectum for this fraction, resulting in a 15.4% greater dose to the rectum for the full treatment

35.600 HDR

- Patient underdose [220186] (cont.)
  - Radiation therapist replaced a catheter with one that was an incorrect length
    - Procedures required a blue catheter with a 1377 mm length, but the new blue catheters are longer than this and must be trimmed down to the correct length
  - Corrective actions included procedure modifications to ensure the correct catheter is of appropriate length, and additional training
  - Patient one had modifications to the rest of the treatment to compensate for the underdose, patient two had no adverse effects

35.600 HDR

- Patient underdose [210482]
  - 277.5 GBq (7.5 Ci) Ir-192 HDR unit
  - Patient prescribed 1400 cGy (rad), administered 1020 cGy (rad)
  - Error message “8C.2 – Dummy park switch or drive failure” displayed during treatment after first 15 channels were delivered
  - Field service engineer suggested reboot of system, not successful
  - AU stopped treatment to avoid leaving patient under general anesthesia, leaving remaining four channels untreated

35.600 HDR

- Patient underdose [210512]
  - 221.26 GBq (5.98 Ci) Ir-192 HDR unit
  - Prescribed 1500 cGy (rad), received 50 cGy (rad)
  - Patient was treated without issue through first channel
  - Error at the start of the second channel, indicating the source position slipped at 0.0 cm mark
  - Treatment paused and test wire was run, no errors indicated
  - Second attempt at treatment returned the same error, treatment was cancelled
  - Source was verified to be in the unit and no additional dose was delivered to the patient or staff
  - Service engineer determined a hardware issue with the active source encoder, which serves as a second check for the movement of the source
  - Encoder replaced, HDR unit determined operational

35.600 HDR

- Wrong site [220085]
  - 237.58 GBq (6.421 Ci) HDR unit
  - Patient intended to receive 600 cGy (rad) to lower third nasal dorsum
  - Patient prescribed 600 cGy (rad) to right nasal sidewall
  - No adverse effects expected

35.600 HDR

- Wrong site [220261]
  - HDR Unit
  - Prescribed 3600 cGy (rad) to the skin of the left scalp
  - Physician misidentified the treatment site, photos taken after biopsy but had healed when trying to identify prior to treatment
  - Potential consequences determined to be potential to develop skin cancer at the treated site in 20-30 years and recurrence of the cancer at the untreated site

35.600 HDR

- Wrong site [220261] (cont.)
  - Patient was offered additional treatment to the carcinoma. But chose observation by dermatologist
  - Corrective actions included creation of an HDR planning policy for dermal brachytherapy
  - Updated commitment to policy to state that HDR skin cancer sites will be reviewed at a peer review meeting before treatment
  - Better photographs of the treatment site will be taken and ambiguous information will require additional verification

35.600 HDR

- Wrong site [220275]
  - 177.6 GBq (4.8 Ci) I-192 HDR Unit
  - Patient has two lesions on the lower right leg
  - First was treated using SBRT without incident
  - Second prescribed 4000 cGy (rad) over 8 fractions
  - First fraction, 500 cGy (rad), unintentionally delivered to the first lesion
  - Discovered when the patient noticed the planning circle had been drawn over the first lesion before the second fraction
  - No adverse effects are expected

35.600 HDR

- Wrong site [220275] (cont.)
  - Root cause was determined to be human error, particularly failure to notice the change in positioning from supine to prone
  - Contribution factors were the proximity of the 2 lesions (1.5 in apart) and that the second lesion was not present during the previous SBRT treatment
  - Corrective actions included adding a pretreatment step for multiple, close lesions, asking the patient to point to the treatment site, and using more verification images of the treatment site

35.600 HDR

- Wrong site [210537]
  - 277 GBq (7.485 Ci) Ir-192 source
  - Prescribed 2100 cGy (rad), delivered in three 700 cGy (rad) treatments
  - First fraction delivered
  - Some point after patient experienced complications from a hysterectomy, treated at a different hospital
  - Did not return for other treatments
  - Oncologist at new hospital determined that the first treatment was off by 3 cm
  - Colon and bowel received dose of 700 cGy (rad)
  - Corrective actions included procedure modification to require CT imaging/review after insertion of HDR applicators

35.600 HDR

- Wrong site [220026]
  - 436.97 GBq (11.81 Ci) Ir-192 HDR unit
  - Patient received a single 250 cGy (rad) fraction to the left hand, instead of the right hand as prescribed
  - Corrective actions included immediate discussion with all clinical staff to verify correct anatomical treatment site regarding all prescriptions

35.600 HDR

- Wrong site [220308]
  - 370 GBq (10 Ci) I-192 HDR Unit
  - Deviation in transfer tube by 2.9 cm discovered, affecting 27 patients
  - Dose to the unintended tissue was determined by recreating the intended plan and comparing to a transfer tube shifted plan
  - Resulted in 267 cGy (rad) of additional dose to unintended tissues per fraction
  - Investigation and corrective actions still ongoing

35.600 PDR

- Patient underdose [220224]
  - 37 GBq (1 Ci) PDR unit
  - Three patients
    - 2982 cGy (rad) prescribed, 256.7 cGy (rad) delivered
    - 36.21 cGy (rad) prescribed, 12.07 cGy (rad) delivered
    - 37.28 cGy (rad) prescribed, 16.72 cGy (rad) delivered
  - Discrepancy between measured treatment distance and treatment plan
  - Root cause determined to be erroneous manual entry in reference table (1248 mm entered vs. 1448 mm intended)
  - Corrective actions included root cause analysis, procedure modification, and additional reference table verification

Medical Events 2022

35.1000 Medical events	**34**
GSR	2
Y-90 Microspheres	
– TheraSphere™	23
– SIR-Spheres®	7

35.1000 Gamma Knife

- Wrong site [220241]
  - Patient prescribed between 20 and 21 Gy (2000 to 2100 rad) to four lesions in the brain
  - Post treatment, discovered that the targeting had been off by 0.5 cm for all lesions
  - Delivered dose to lesions between 8 and 15 Gy (800 to 1500 rad)
  - Max dose range to unintended healthy tissue was 21.82 to 27.09 Gy (2182 to 2709 rad)

35.1000 Gamma Knife

- Wrong site [220241] (cont.)
  - Root cause was shifting of coregistration of images between intended target and treatment parameters
    - Discovered after surgery
  - No adverse effects are expected but patient will be monitored
  - Corrective actions included updated treatment procedures to include review and approval of treatment plan by two of three team members that involve coregistration of CT/MRI images

35.1000 Gamma Knife

- Wrong site [220484]
  - Patient treated for 10 brain lesions, patient fell asleep during treatment of first 4 lesions
  - Patient woke up for the fifth treatment but no sufficient movement was recorded to stop/delay treatment
  - Treatment later paused to allow the patient to use the restroom, during which the therapist noticed the frame had moved from its original position
  - Remainder of the treatment was cancelled, new CT was performed, and new treatment plan was developed for the remaining 4 lesions, which were treated without incident
  - Review of the treatment indicated that 4 lesions were treated initially, 2 followed the patient waking up, and the remaining 4 were treated after the re-planning

35.1000 Gamma Knife

- Wrong site [220484] (cont.)
  - Potential effects were determined on a most likely and worst-case scenario
    - Most likely – only 2 lesions affected by movement
    - Worst-case – 6 initial lesions affected by movement
  - In the most likely scenario, the two lesions received slightly more dose due to a slightly higher volume of brain tissue exposed and there was no effect on the other lesions
  - In the worst-case scenario, two lesions would be underdosed by over 50% and would have significantly high risk of recurrence
  - The patient has been followed and has shown no detrimental effects from this event
  - This event is still under investigation

35.1000 TheraSphere™

- Y-90 TheraSphere™ overdose [220181]
  - Patient prescribed 2.228 GBq (60.22 mCi), received 2.84 GBq (76.7 mCi)
  - When administering microspheres to three liver segments, it was determined that the segment had been misidentified due to variant anatomy
  - Segment 7 received more dose than expected but all three targets had received an appropriate segementectomy dose
  - Root cause was determined to be failure to identify variant anatomy during treatment
  - Corrective actions included secondary review of pre-treatment mapping and angiography of any administration where the location of the catheter is questioned
  - If this is not effective, the AU will perform a 3d cone beam CT to confirm the area to be treated
  - No adverse effects were expected

35.1000 TheraSphere™

- Y-90 TheraSphere™ overdose [210494]
  - Patient prescribed 2 administrations to different segments of the liver, 1 GBq (27 mCi) and 2.72 GBq (73.4 mCi)
  - Administered 2.18 GBq (59 mCi) and 4.4 GBq (119 mCi) respectively
  - The doses had been ordered with an incorrect calibration date
  - Root cause was determined to be a failure to confirm the calibration date and a failure to check the that the prescribed dose matched the measured dose during pre-treatment checks
  - Patient was followed and no adverse effects were noted
  - Corrective actions included updating Y-90 worksheets to add a new verification of dose-in-hand rather versus the written directive, and an update to the dose ordering process requiring a second person to give their signature
  - Personnel were trained on these new procedures

35.1000 TheraSphere™

- Y-90 TheraSphere™ overdose [220207]
  - Patient prescribed 1.94 GBq (52.43 mCi), received 2.81 GBq (75.95 mCi)
  - Patient intended to receive 2 vials of microspheres for the administered dose
  - WD erroneously accounted for only one vial
  - Administered activity was within 2% of planned activity
  - Root cause was determined to be human error
  - Corrective actions included personnel training and procedure updates

35.1000 TheraSphere™

- Y-90 TheraSphere™ overdose [220173]
  - Patient prescribed 0.355 GBq (9.6 mCi), received 2.17 GBq (58.6 mCi)
  - Two patients were due to receive Y-90 treatment on the same day
    - Patient A with 2 vials, Patient B with 3 vials
  - Patient A was prescribed 0.355 GBq (9.6 mCi) and 1.3 GBq (35.2 mCi), but the first vial was mistakenly swapped with one of Patient B's vials
  - The WD prescribed 12,000 cGy (rad) to segments 2 and 3 but received 73,660 cGy (rad)
  - This dose was considered clinically acceptable, and no adverse effects are expected
  - Patient B's treatment was cancelled

35.1000 TheraSphere™

- Y-90 TheraSphere™ overdose [220173] (cont.)
  - Corrective actions included requiring a signed verification of dose activity by two techs, with a temporary requirement that one be a supervisor or manager
  - Additionally, all dose vials are now required to be re-verified in the vent of handoff between certified NMTs
  - Y-90 standard operating procedure was revised and all staff and Aus were trained on the updates
  - For 90 days following the event, a supervisor checked the cart, documentation, and calibration instrumentation for accuracy prior to transport to the IR suite
  - Monthly audits occurred for 90 days to determine effectiveness of these actions, after which quarterly audits continued

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [210491]
  - Patient prescribed 1.3 GBq (35.1 mCi), received 0.533 GBq (14.4 mCi)
  - Vial septum failed under pressure during administration
  - No effects were expected
  - Root cause was determined to be failure to develop, implement, and maintain procedures
  - Corrective actions included revision of procedures to specify the correct needle gauge and revision of emergency procedures

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [210480]
  - Patient prescribed 1.66 GBq (44.8 mCi), received 0.692 GBq (18.7 mCi)
  - Physician noted that there was greater resistance during administration but no stoppage occurred due to intervention or patient
  - Tubing and connections were checked, no cause for the resistance was found
  - Overflow bottle did overflow but no activity was measured
  - Dose rate at vial was zero after administration and no contamination was found

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [210480] (cont.)
  - Investigation found that microspheres had built up at the distal and proximal ends of the catheter, but no reason could be found
  - Manufacturer noted that the catheter was within the recommended size
  - Corrective actions included more flushes during treatment

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220054]
  - Patient prescribed 1.45 GBq (39.24 mCi), received 1.03 GBq (27.72 mCi)
  - Treatment proceeded without incident, but post-treatment survey of waste revealed 0.43 GBq (11.52 mCi) of Y-90
  - No contamination was detected
  - No adverse effects are expected

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [210529]
  - Patient prescribed 4.08 GBq (110.27 mCi), received 2.57 GBq (69.46 mCi)
  - Treatment proceeded without incident
  - Post-treatment surveys revealed residual activity and gave estimates of the administered dose
  - Root cause was determined to be flow issue in the microcatheter, causing the microspheres to precipitate out
  - No adverse effects to the patient are expected

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220182]
  - Patient prescribed 379.99 MBq (10.27 mCi), received 260.11 MBq (7.03 mCi)
  - AU noticed sluggish flow during first saline flush, possibly due to kinking in the microcatheter
  - No contamination was identified, and the AU was satisfied with the dose delivered
  - Root cause was determined to be small treatment volume and small vessel treated
  - More than 30 psi is required to push microspheres into small vessels, but the built-in pressure valve did not apply pressure greater than 30 psi
  - No adverse effects were expected

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220264]
  - Patient received only 26% of prescribed dose
  - Treatment went according to plan, post-treatment surveys revealed that microspheres did not come out of the tubing as designed
  - All proper procedures were followed, no kinks in tubing could be identified, and the AU had used a larger catheter than required
  - Over 70% of the microspheres remained in the delivery device
  - No root cause could be identified but investigations determined that the most likely cause was equipment failure
  - No corrective actions were identified

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220390]
  - Patient prescribed 44,000 cGy (rad), received 35,180 cGy (rad).
  - During preparation, oncology nurse expelled some liquid onto gauze to remove bubbles from the treatment tubing
  - The loss of activity resulted in a smaller delivered activity
  - No adverse effects were expected, and no additional dose was needed
  - Investigation determined that proper procedure had been followed and it was not clear whether the vent was caused by human error or product defect

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220387]
  - Patient prescribed 1.27 GBq (34.4 mCi), received 111 MBq (3 mCi)
  - Procedure was halted prematurely, and surveys of the waste and room were taken
  - No contamination was found, and microspheres were observed clustered in the hub
  - Correct microcatheter was used
  - Waste survey was used to approximate dose delivered
  - Root cause was determined to be microsphere clumping between lines E and D in the kit

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220410]
  - Patient prescribed 1.77 GBq (48 mCi), received 1.05 GBq (28 mCi)
  - Microspheres clumped in catheter and AU was unable to administer the full dose
  - Root cause was determined to be a microcatheter with a curved tip that ended up at the vessel wall, blocking the flow of microspheres
  - Corrective actions included discontinuing use of that type of microcatheter

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [210493]
  - Patient prescribed 1.26 GBq (34.1 mCi), received 0.895 GBq (24.2 mCi)
  - Surveys after the administration noted that microshperes were held up in the catheter
  - Root cause was determined to be clumping of microspheres in the catheter due to problems in the procedure
  - A copy of IN-19-12 was provided to understand the issue and help prevent future incidents

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [210486]
  - Patient prescribed 3 GBq (81.08 mCi), received 1.96 GBq (52.90 mCi)
  - Surveys of the container revealed a higher than expected dose after the administration
  - Delivery kit was shipped to manufacturer after decay
  - Root cause was determined to be intentional use of a smaller catheter than advised (0.3mm), resulting in microspheres being held up in the line
  - Physician determined that the dose delivered was effective
  - No corrective actions were taken

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [210500]
  - Patient prescribed 809.93 MBq (21.89 mCi), received 509.86 MBq (13.78 mCi)
  - One of four treatments to different lobes of the liver
    - Three other treatments had no complications
  - Physician attempted to use 2.0 Fr. Truselect microcatheter for an hour to access artery but was unsuccessful
  - Fell back on a 1.7 Fr. Echelon microcatheter, where some of the microspheres were held up in the smaller catheter
  - Other treatment options were considered, but the decision to use the smaller catheter was determined by the physician to be medically necessary
  - No adverse effects are expected and no corrective actions were put in place

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220039]
  - Patient prescribed 1.93 GBq (52.16 mCi), received 0.49 GBq (13.24 mCi)
  - Treatment was prematurely terminated due to unwinding of male Leur lock connector
  - A second WD was created to compensate for the underdose and this treatment was successful
  - Information of this event was circulated to all impacted licensees
  - Root cause was determined to be a defective Leur lock
  - The event was not reported initially due to insufficient WD procedures
  - Corrective actions included casing use of the affected administration set

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220021]
  - Patient was successfully administered two doses of microsphere but the third only administered 5% of the dose
  - The microspheres were caught up in the tubing from the vial

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220127]
  - Patient prescribed 2.93 GBq (79.19 mCi), received less than 1% of prescribed
  - AU noticed resistance during administration and halted the treatment
  - Microspheres were observed clumped in the first 2 in of the delivery catheter
  - Second dose ordered and delivered successfully
  - No contamination was identified
  - Root cause was determined to be use of a catheter smaller than the recommended catheter by the manufacturer
  - Corrective actions included discontinuation of microcatheters with inner diameter smaller than 0.5 mm in accordance with recommendations
  - No adverse effects to the patient were expected

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220091]
  - Patient prescribed 0.51 GBq (13.78 mCi), received 0.16 GBq (4.32 mCi)
  - Discovered during a review of microsphere procedures, licensee incorrectly assumed this was not reportable because they revised treatment plan and WD after treatment
  - Root cause was determined to be use of a smaller than recommended catheter
  - AU stated that dose was medially satisfactory and then smaller diameter catheter was necessary to treat the patient
  - Corrective actions included providing additional training to staff

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220087]
  - Patient prescribed 0.3 GBq (8.11 mCi), received 0.11 GBq (2.97 mCi)
  - Discovered during a review of microsphere procedures, licensee incorrectly assumed this was not reportable because they revised treatment plan and WD after treatment
  - Root cause was determined to be use of a smaller than recommended catheter
  - AU stated that dose was medially satisfactory and then smaller diameter catheter was necessary to treat the patient
  - Corrective actions included providing additional training to staff

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220190]
  - Patient prescribed 12,000 cGy (rad), received 9,420 cGy (rad)
  - Stasis was not reached, and no apparent cause was identified
  - Au had written that 12,000 cGy (rad) was the desired dose on the WD, but the dose received from the manufacturer had a maximum expected dose of 11,000 cGy (rad)
  - If the WD had been updated with this dose, then the administration would have not tripped the ME criteria
  - Corrective actions included training to WD updates

35.1000 TheraSphere™

- Y-90 TheraSphere™ wrong site [220296]
  - Patient prescribed 1.45 GBq (39.2 mCi) to the right lobe of the liver for 14,800 cGy (rad), received 24,000 cGy (rad) to the left lobe of the liver
  - Root cause was determined to be variant anatomy
  - Patient was brought back in to treat the correct lobe of the liver

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® overdose [220280]
  - Patient prescribed 2.2 GBq (59.46 mCi), received 5.07 GBq (137 mCi)
  - NM ordered a full unit dose and mistakenly administered the full dose during the treatment
  - Dose was not verified prior to administration and WD was incorrectly filled out with received and ordered doses
  - Root cause was determined to be human error
  - Corrective actions included implementation of a new procedure

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® overdose [210492]
  - Patient prescribed 0.4 GBq (10.81 mCi) and 1.6 GBq (43.24 mCi), received 0.51 GBq (13.78 mCi) and 2.19 GBq (59.19 mCi)
  - A calculational error occurred when converting from GBq to mCi, resulting in the larger doses
  - Corrective actions included an updated WD that explicitly lists the conversion factor from GBq to mCi, and the conversion to be performed by the NMT not just the manufacturer representative
  - No adverse effects were identified or expected

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220404]
  - Patient prescribed 0.5 GBq (13.51 mCi), received between 0.386 (10.43 mCi)
  - Root cause was determined to be a clogged catheter
  - Corrective actions included implementation of a new quality management plan
  - No adverse effects are expected

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220351]
  - Patient prescribed 599.4 MBq (16.2 mCi), received 469.9 MBq (12.7 mCi)
  - Error discovered during post-treatment calculations
  - No root cause could be determined
  - No adverse effects were expected

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220231]
  - Patient prescribed 370 MBq (10 mCi), received 230.51 MBq (6.23 mCi)
  - Prior to treatment, contrast was injected and no leakage was observed
  - During the administration, the doctor noticed a small leak at the Leur lock connection
  - The Radiation Safety staff was notified and the doctor tightened the connector and continued the procedure after changing gloves
  - The remainder of the microspheres were administered without incident
  - Contaminated materials were then removed and surveyed to estimate the dose not delivered

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220231] (cont.)
  - The room was surveyed and found to have no contamination
  - Root cause was determined to be a lack of clear written instructions in the procedures
  - Corrective actions included an update to the procedures to include steps for checking the connections to the delivery system
  - No adverse effects were expected

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220189]
  - Patient prescribed 261.59 MBq (7.07 mCi), received 194.99 MBq (5.27 mCi)
  - Apparent cause was complicated patient vasculature, inhibiting flow of microspheres
  - No adverse effects were expected

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220056]
  - Patient prescribed 3.25 GBq (87.84 mCi), received 1.55 GBq (41.89 mCi)
  - Procedure was halted due to occlusion of microspheres in delivery line
  - This treatment was the largest ever dose to date at this treatment facility
  - The vial was at maximum volume and the fluid appeared highly viscous
  - Root cause was determined to be too many microspheres in the vial to be properly agitated or a dysfunctional stop cock
  - Corrective actions included modification of procedures to split large doses into 2 separate vials
  - Patient was administered another dose to compensate, no adverse effects expected

35.1000 SIR-Spheres®

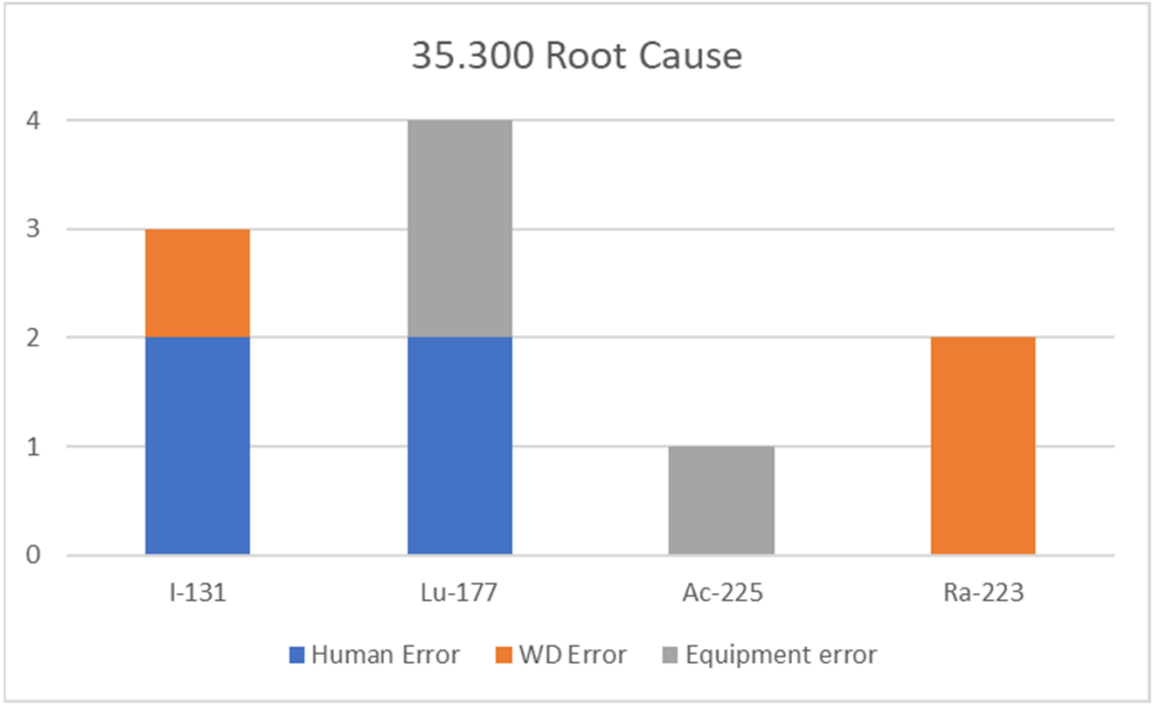
- Y-90 SIR-Spheres® underdose [210507]
  - Patient prescribed 299.7 MBq (8.1 mCi), received 233.1 MBq (6.3 mCi)
  - Procedure occurred without incident, no stasis
  - Investigations determined that a member of the staff noticed a blob of microspheres close to the vial before dose delivery
  - Manufacturer was notified and recommended gentle shaking of the vial before delivery
  - AU determined that the dose delivered was effective
  - Corrective actions included checking the vial prior to delivery and following manufacturer recommendations to shake the vial gently if accumulation is observed
  - No adverse effects were expected

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [210474]
  - Patient prescribed 185 MBq (5 mCi), received 135.79 MBq (3.67 mCi)
  - Remaining microspheres held up in delivery system
  - Investigation noted that the dose was unusually small compared to previous procedures
  - The amount of remaining microspheres was approximately the same as in previous procedures, but the smaller size of the initial dose resulted in a reportable underdose
  - Corrective actions included additional saline flushes to minimize residual microspheres and the addition of 20% more activity for low dose prescriptions (<370 MBq (10 mCi)) to account for anticipated residual microspheres
  - Additionally, the licensee implemented more frequent monitoring of hands-on personnel to identify potential contamination
  - No adverse effects were expected, and no additional dose was required

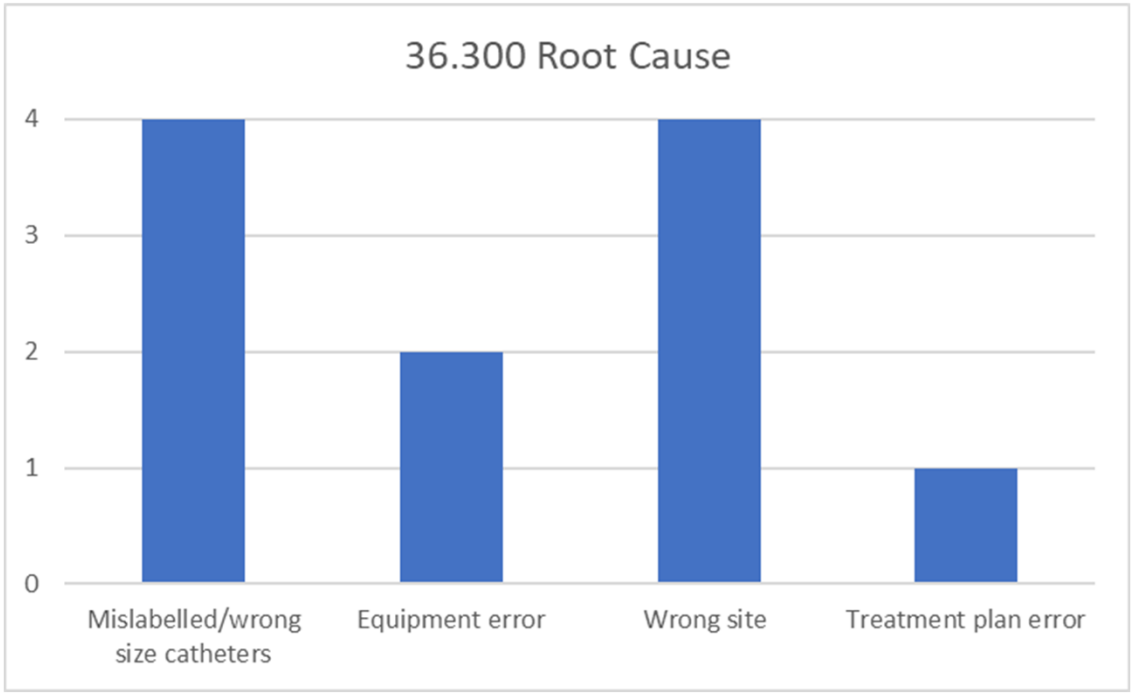
Summary

- 35.300
  - Delivered intended dose but incorrect WD
  - Full dose administration of Lu-177 but reduced dose on WD
  - Ac-225 difficulties with lead shielded syringe, resulting in leakage



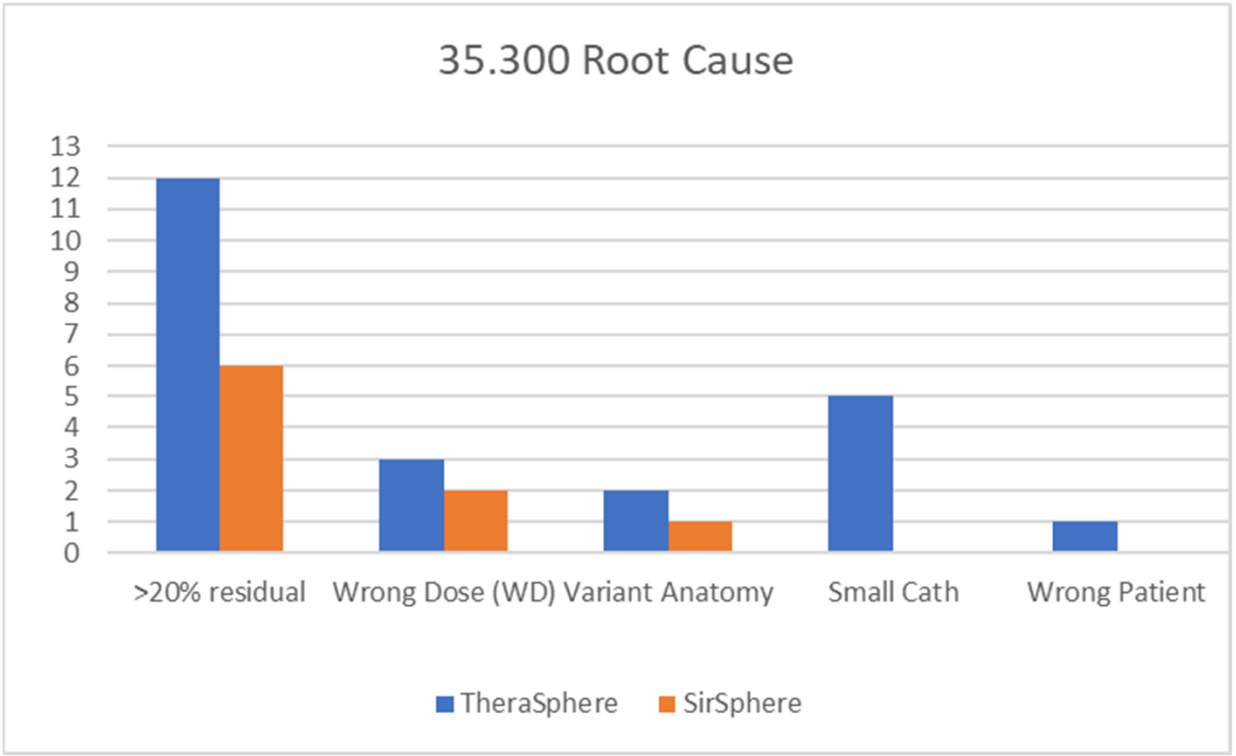
Summary

- 35.600
  - 4 misidentified lesion sites
  - Use of incorrect tube/catheter lengths
  - Multiple patients affected by single medical event, catheter/tube length problems



Summary

- 35.1000
  - Primarily Theraspheres, primarily underdoses
  - 4 events due to use of smaller than recommended catheters
  - 2 events due to malfunctioning Luer locks
  - 2 events due to unusually small doses
  - 3 of 6 overdose events were due to incorrect WD



Acronyms

- µCi – microcurie
- AMP – authorized medical physicist
- AU – Authorized User
- Cs-131 – Cesium-131
- cGy – centiGray
- CT – Computed tomography
- FY – Fiscal Year
- GBq – Giga Becquerel
- Gy – Gray
- HDR – High Dose Rate Remote Afterloader

Acronyms

- I-125 – Iodine-125
- I-192 –Iridium-192
- IVB – Intravascular Brachytherapy
- Lu-177 – Lutetium-177
- MBq – Mega Becquerel
- µCi - microcurie
- mCi – millicurie
- NMT – Nuclear medicine technician
- RSO – radiation safety officer
- SI units – International System of Units
- WD- Written Directive
- Y-90 – Yttrium-90

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QUESTIONS?