
# Status of Medical Events FY 2023

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# Medical Events FY 2018 - 2023

| | FY18 | FY19 | FY20 | FY21 | FY22 | FY23 |
|---|---|---|---|---|---|---|
| 35.200 | 0 | 1 (8*) | 0 | 4 | 0 | 1 |
| 35.300 | 2 | 9 | 2 | 10 | 10 | 11 |
| 35.400 | 11 (13*) | 5 | 6 | 4 | 1 | 3 |
| 35.600 | 10 | 9 (10*) | 13 | 5 | 11 (40*) | 8 |
| 35.1000 | 25 (26*) | 32 | 27 | 41 | 34 | 36 |
| Total | 48 | 56 | 48 | 64 | 56 | 59 |

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

# Medical Events 2023

**35.200 Medical events** **1**

I-123 1

# 35.200 I-123

- Wrong Drug [230114]
  - Patient prescribed I-123 scan, received 162.8 MBq (4.4 mCi) I-131 TBI scan
  - Scheduled in electronic medical system for TBI scan with Thyrogen
  - Patient was administered the first dose of Thyrogen, however the technologist realized that the patient had their thyroid before the second injection of Thyrogen
  - Administered the I-131 injection and the radiologist discovered that the patient had been administered the wrong drug when reviewing the images
  - The dose to the thyroid was estimated to be 150 Gy (15,000 rad)

# 35.200 I-123

- Wrong Drug [230114] (cont.)
  - Patient followup reported no adverse effects to the patient
  - Root cause was determined to be human error; protocol to have all patient records and lab work completed before administration was not followed
  - Additionally, the written directive did not specify the radioisotope, only that a total body iodine scan had been prescribed
  - Corrective actions included the creation of a new form requiring the inclusion of all relevant patient labs to be completed before signing the written directive

# Medical Events 2023

| | |
|---|---|
| **35.300 Medical events** | **11** |
| Lutetium-177 | 9 |
| I-131 | 2 |

# 35.300 Lu-177

- Wrong Drug [230424]
  - One patient was prescribed commercially available Lu-177 Dotatate, another prescribed Lu-177 dotatate under a new investigational new drug label
  - Patient prescribed the commercially available Lu-177 was instead administered the investigational drug
  - The patient was given the correct activity, chemical form, and route of administration
  - Root cause was determined to be human error
  - No adverse effects are expected
  - Additional notifications were made to the Institutional Review Board, considering the involvement of an investigational drug product

# 35.300 Lu-177

- Patient overdose [230370]
  - Prescribed 5.92 GBq (160 mCi), administered 7.65 GBq (206.7 mCi)
  - RSO indicated that the technologist did not follow the written directive to verify activity before injection
  - Typical injection uses 7.4 GBq (200 mCi), technologist did not recognize the updated dose
  - Corrective actions included updated procedures

# 35.300 Lu-177

- Patient underdose [230360]
  - Patient prescribed 7.4 GBq (25 mCi), received 70-75% of the dose
  - Administering Lu-177 via syringe pump
  - 20 minutes into the injection, patient reported a wet feeling on their hand
  - Leak was traced to the connection between the syringe pump and the patient's IV site
  - Bedding and materials had absorbed a majority of the leak and spill response protocols were initiated
  - Estimates of the material remaining in the vial, the contamination on the bedding, and patient dose rate measurements post-treatment suggested an underdose of 25-30%
  - Skin exposure was estimated to be under 10 cSv (rem)
  - Corrective actions included updated procedures and training, and clarification that all future therapy administrations will be through secured connections

# 35.300 Lu-177

- Patient underdose [230102]
  - Prescribed 7.4 GBq (100 mCi), administered 5.83 GBq (157.57 mCi)
  - During the administration, the technologist noticed drips from the tubing
  - Investigation indicated the patient had received 21.22% less dose than prescribed
  - Root cause was determined to be leaky tubing, additionally tubing from the same lot was also found to be leaky
  - Corrective actions included removing that lot from use and notifying the vendor of the defect
  - Additionally, the licensee updated procedures to visibly check for leaks

# 35.300 Lu-177

- Patient underdose [230023]
  - Patient prescribed 7.4 GBq (200 mCi), received 4.48 GBq (121 mCi)
  - The normal apparatus used for administering Pluvicto was not available due to supply chain issues
  - A similar, pressurized apparatus was used instead
  - Leak was identified at the rubber septum of the vial in the shielded storage container
  - Root cause was determined to be pressurization of the vial, manufacturer does not recommend pressurizing the vial
  - Another dose of Pluvicto was administered to replace the underdosed administration and was administered without incident

# 35.300 Lu-177

- Patient underdose [230023]
  - Patient prescribed 7.4 GBq (200 mCi), received 4.77 GBq (129 mCi)
  - The normal apparatus used for administering Pluvicto was not available due to supply chain issues
  - A similar, pressurized apparatus was used instead
  - Leak was identified at the rubber septum of the vial in the shielded storage container
  - Root cause was determined to be pressurization of the vial, manufacturer does not recommend pressurizing the vial
  - Patient will be monitored during the rest of their treatment regimin and appropriate equipment will be used for following treatments

# 35.300 Lu-177

- Wrong drug [220531]
  - 2 patients, one prescribed 7. Gbq (200 mCi) of Lu-177 dotatate, another prescribed 7.4 GBq (200 mCi) of Lu-177 vipivotide tetraxetan
  - Vials were switched and each patient was administered the incorrect drug
  - Root causes were determined to be complacency and lack of training
  - Additionally, both doses were identical and the shipping containers were similarly colored
  - Corrective actions included implementing a new scheduling process so Lutathera and Pluvicto treatments are not scheduled on the same day and institution of a dual verification process
  - Additionally, the licensee provided reeducation on package checks and patient verification

# 35.300 Lu-177

- Patient underdose [220448]
  - Patient prescribed 7.4 GBq (200 mCi), received 3.92 GBq (106 µCi)
  - Injection occurred without incident
  - Post-treatment investigation discovered residual radiopharmaceutical in the injection tubing giving an estimate of the underdose
  - Root cause was determined to be human error
  - Corrective actions included increasing the mandatory saline flush from 25 mL to 250 mL, staff training, and strict vetting of technologists for therapy administrations

# 35.300 Lu-177

- Patient underdose [220432]
  - Patient prescribed 7.4 GBq (200 mCi), received 5.11 GBq (138 mCi)
  - Injection occurred without incident
  - Post-treatment investigation discovered residual radiopharmaceutical in the injection tubing giving an estimate of the underdose
  - Root cause was determined to be human error
  - Corrective actions included increasing the mandatory saline flush from 25 mL to 250 mL, staff training, and strict vetting of technologists for therapy administrations

# 35.300 I-131

- Patient overdose [230279]
  - Prescribed 2.78 GBq (75 mCi), administered 3.7 GBq (100 mCi)
  - 2 dose of I-131 were prepared for 2 separate patients
  - While preparing the dose for the first patient, the technologist mistakenly assayed the second dose
  - The first patient was inadvertently administered the dose intended for the second patient
  - The mistake was discovered prior to treating the second patient
  - Root cause was determined to be human error
  - Corrective actions included staff training on time-out procedures and posting a physical copy of the time-out procedures on the wall in the therapy room

# 35.300 I-131

- Patient overdose [220338]
  - Patient prescribed 740 MBq (20 µCi), received 780.7 MBq (21.1 µCi)
  - Patient received the intended dose but the written directive incorrectly specified “20 µCI” instead of “20 mCi”
  - No adverse effects are expected
  - Corrective actions included combining WD checklist and WD prescription into one form
  - AU also now is required circle the word millicurie or microcurie on the form, and the technologist has to sign off on dose verification

# Medical Events 2023

| | |
|---|---|
| **35.400 Medical events** | **3** |
| Eye Plaque | 1 |
| Cs-131 Brachytherapy | 2 |

# 35.400 I-125 Eye Plaque

- Patient underdose [230335]
  - Prescribed 8,500 cGy (rad), received 5,700 cGy (rad)
  - Licensee believes the eye plaque may have shifted over the seven day treatment
  - Update required

# 35.400 Cs-131

- Patient underdose [230354]
  - Prescribed 11,500 cGy (rad), received 5,750 cGy (rad)
  - Planned to implant a total of 98 C-131 seeds with a total of 10.46 GBq (282.6 mCi)
  - 37 seeds unused after the treatment, 70 total were implanted
  - Root cause was determined to be swelling and excessive bleeding causing coagulated blood in the Mick applicator
  - Corrective actions included revising procedures

# 35.400 Cs-131

- Patient underdose [230219]
  - Prescribed 6,000 cGy (rad), received 3,700 cGy (rad)
  - Patient was implanted with seeds totaling 1.42 GBq (39.5 mCi)
  - Following implantation, the patient was diagnosed with a medical condition that necessitated the immediate removal of the seeds
  - All seeds were accounted for, and actual dose was calculated
  - Incident was discovered during a routine safety inspection
  - No corrective actions were taken

# Medical Events 2023

| | |
|---|---|
| **35.600 Medical events** | **8** |
| HDR | 8 |

# 35.600 HDR

- Wrong Site [230417]
  - 185 GBq (5 Ci) I-192 HDR Unit
  - Cylinder inadvertently shifted during a vaginal treatment by 3.5 cm
  - Update required

# 35.600 HDR

- Wrong site [230365]
  - 192.4 GBq (5.2 Ci) Ir-192 HDR unit
  - Patient prescribed 1,800 cGy (rad) in three fractions
  - CT planning, plan review, time-out, and device insertion (including depth verification) were all completed without incident
  - During the first fraction the patient notified the AU that the cylinder was in the wrong place
  - The administration was stopped 111 seconds into the treatment and it was discovered that the cylinder had been placed into the rectum instead of the vagina.

# 35.600 HDR

- Wrong site [230365](cont.)
  - After removal of the device and discussion with the team, treatment resumed with the correct placement of the device
  - The remaining fractions were adjusted and the dose to the rectum was estimated at 239 cGy (rad)
  - No adverse effects are expected
  - Corrective actions included additional training, including verification the the device is in the correct anatomy

# 35.600 HDR

- Patient overdose [230255]
  - Patient was prescribed 500 cGy (rad) in three fractions for a total of 1500 cGy (rad) to the keloid skin surface
  - Mistakenly administered the full 1500 cGy (rad) in one fraction
  - Medical physicist started treatment plan based on AU intention
  - Original MP was called away to another treatment and a second MP finished the treatment plan
  - Second MP set the prescription to 15 Gy, not realizing that this was the total dose, not a fraction
  - Mistake was caught during post-treatment bookkeeping

# 35.600 HDR

- Patient overdose [230255](cont.)
  - No adverse effects are expected
  - Root cause was determined to be human error
  - Corrective actions included specifying that a single MP be present throughout the whole planning and treatment process, the implementation of a formal hhand-off process, more descriptive process checks, and a mandated pre-treatment time-out

# 35.600 HDR

- Patient underdose [230166]
  - Patient prescribed four treatments of 500 cGy, received 156 cGy on the fourth treatment
  - HDR unit gave an error during the fourth treatment indicating a source retraction issue
  - The right and left partial ring treatments were administered but not the tandem
  - Root cause was determined to be failure of the HDR motors
  - Additionally, the licensee used an applicator that was not approved for use with the Flexitron system, which resulted in the source capsule becoming stuck
  - Corrective actions included equipment testing, a hold on the program pending root cause analysis, evaluation of policies and procedures, and additional training

# 35.600 HDR

- Patient underdose [230104]
  - 251.6 GBq (6.8 Ci) Ir-192 HDR unit
  - Prescribed 5 fractions of 600 cGy (rad), received less than 50% of the fraction for the first two fractions
  - Planning had mapped the channels to specific catheters, but post-treatment review discovered that during the administration the channels had been incorrectly mapped
  - Adjustments were made in the following fractions to ensure appropriate tumor coverage and tissue sparing
  - No adverse effects are expected
  - Corrective actions included updated procedures and checklists

# 35.600 HDR

- Patient Underdose [230062]
  - 275.28 GBq (7.44 Ci) HDR unit
  - Prescribed 1,350 cGy (rad), administered 326.56 cGy (rad)
  - During treatment the AU observed that the transfer stretcher was pitched towards the patient's head and interrupted the treatment
  - 15 of 17 needles had been extracted approximately 2 centimeters
  - Patient was monitored for any adverse effects, but none were expected

# 35.600 HDR

- Patient Underdose [230062](cont.)
  - Root cause was determined to be an issue with the hydraulics in the patient transfer stretcher, with lack of attention to the patient as a contributing factor
  - Corrective actions included amending the procedures to maximally lower the stretcher during treatment
  - The state also recommended evaluing the roles of individuals present during treatment to ensure continuous patient monitoring

# 35.600 HDR

- Patient Underdose [220508]
  - 329.3 GBq (8.9 Ci) Ir-192 HDR unit
  - Prescribed 750 cGy (rad) per fraction, administered 12.7 cGy (rad) in the third fraction
  - During treatment, the HDR unit was unable to detect one of the transfer tubes connecting it to the applicator, resulting in a partial delivery of the fraction
  - The field service engineer determined that the HDR's unit selector should be recalibrated, after which the unit functioned correctly
  - The patient was then successfully treated the following day

# 35.600 HDR

- Patient Overdose [220495]
  - 327.5 GBq (8.85 Ci) I-192 HDR unit
  - Prescribed five fractions of 600 cGy (rad), received the full 3000 cGy (rad) in a single fraction
  - During the treatment the MP misread the written directive and delivered the full 300 cGy
  - Patient was monitored following the treatment and no adverse effects were observed

# 35.600 HDR

- Patient Overdose [220495](cont.)
  - Root cause was determined to be human error, the licensee uses two treatment planning systems and the MP read the secondary plan instead of the primary plan
  - Corrective actions included having one person perform the planning and another perform the verification, with each signing off before the treatment.
  - Additionally, a generic table of expected treatment times based on dose was developed
  - The state reported that the corrective actions taken were suitable

# Medical Events 2023

| **35.1000 Medical events** | **36** |
|---|---|
| Seed localization | 1 |
| Intravascular Brachytherapy | 1 |
| GSR | 1 |
| Y-90 Microspheres | |
| – TheraSphere™ | 24 |
| – SIR-Spheres® | 9 |

# 35.1000 Radioactive Seed Localization

- Failure to Explant [230348]
  - Patient went into surgery to have localization seed explanted the day after it had been implanted
  - 10 months later, it was discovered that the seed remained in the patient
  - The previous surgery had removed a clip, instead of the seed
  - The calculated dose to the tissue was 74 cGy (rad)
  - The seed will be removed in a future planned surgery

# 35.1000 IVB

- Wrong site [230291]
  - Patient prescribed 2,300 cGy (rad), delivered to the wrong treatment site
  - 3.62 GBq (97.84 mCi) Sr-90 source
  - During treatment, the cardiologist used fluoroscopy to determine the treatment site
  - Post-treatment review of the images could not accurately assess the location of the source
  - Prescribing physician determined that the dose had been delivered to another part of the vasculature proximal to the intended location

# 35.1000 IVB

- Wrong site [230291](cont.)
  - No permanent damage is expected
  - Root cause was determined to be human error; the cardiologist misread the images due to poor quality and obscuration of the images by medical equipment
  - Corrective actions included additional training, procedure modifications, and an agreement for an independent assessment of the dose by a medical physics consultant

# 35.1000 Gamma Knife

- Patient Underdose [230108]
  - Patient prescribed 1,500 cGy (rad), delivered 44.11 cGy (rad)
  - Planned for 13 shots, unit malfunctioned after completing 3 shots
  - Error could not be resolved by licensee and required service
  - Technician identified and repaired a worn sector drive assembly
  - Patient was rescheduled for successful treatment

# 35.1000 Y-90 TheraSphere™

- Y-90 underdose [220492]
  - Patient prescribed 15,000 cGy (rad), received 7,905 cGy (rad)
  - Root cause was determined to be significant back pressure with overflow of saline into the “pop off” vial
  - This backpressure was significant enough to prevent delivery of the full dose
  - No adverse effects are expected
  - Corrective actions included monitoring of the “pop off” vial during administration for back pressure in addition to normal checks

# 35.1000 Y-90 TheraSphere™

- Y-90 underdose [230361]
  - Patient prescribed 2.11 GBq (57.03 mCi), received 0.927 GBq (25.05 mCi)
  - Investigation is ongoing

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230425]
  - Patient prescribed 1.7 GBq (45.92 mCi) ,administered 1.3 GBq (35.15 mCi)
  - Administration occurred without incident and the delivered dose was determined to be clinically effective
  - Post-treatment calculations revealed the underdose, imaging of the waste determined the majority of the remaining dose was in the vial
  - Inspectors concluded that the practitioner did not tap the vial sharp enough against a hard surface prior to administration (i.e. inadequate agitation of the vial)
  - Corrective actions included checklist revision to better describe dose vial preparation and additional training

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230395]
  - Patient prescribed 40,700 cGy (rad), received 31,320 cGy (rad)
  - AU discovered that a significant amount of residual dose was in the vial post-treatment
  - Delivery kit was returned to the manufacturer where a kink was discovered in the microcatheter
  - Additionally, there was evidence of low flow of microspheres during delivery
  - No adverse effects are expected, the dose received was therapeutic
  - Corrective actions included observation of the next case by the lead IR physician involving this AU to ensure correct administration

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230392]
  - Patient prescribed 6.7 GBq (181.08 mCi), received 5.02 GBq (135.81 mCi)
  - Root cause was suspected to be due to air in the tubing during the administration
  - No adverse impacts to the patient are expected, the dose was determined to be medically sufficient

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230363]
  - Patient prescribed 1.24 GBq (33.51 mCi), received 0.715 GBq (19.32 mCi)
  - During treatment, the microspheres required higher pressure to deliver and the spillover vial had a high volume of microspheres
  - Post-treatment surveys confirmed that a large portion of microspheres had not been delivered
  - Root cause was suspected to be failure of the needle or equipment, since no other operating steps showed signs of failure
  - The patient was scheduled for a follow-up treatment
  - The equipment will be returned to the manufacturer when sufficiently decayed

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230357]
  - Patient prescribed 17,500 cGy (rad), received 3,170 cGy (rad)
  - Physician noted resistance during administration and the pressure vial was noticed to be filling with saline
  - Treatment was stopped and a plug of microspheres was discovered in the line
  - The plug was dislodged, and saline was flushed eight times, but the procedure was terminated since it was clear the administration was not successful
  - A follow-up procedure was scheduled for the patient
  - The treating equipment was returned to the manufacturer for investigation

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ wrong site [230341]
  - Patient prescribed 3.07 GBq (83 mCi) to the right lobe of the liver, received the dose to the left lobe of the liver
  - Tc-99m planning study indicated primary deposition in the right lobe of the liver with some deposition in the left lobe
  - However, primary distribution was to the right lobe of the liver
  - Treatment had been planned to the right lobe under a different written directive, so no adverse effects to the patient are expected

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ wrong site [230341](cont.)
  - Corrective actions included a new process where nuclear medicine to contact interventional radiology when images indicate any activity in an unintended area
  - Additionally, all AUs have been directed to consider all distribution pathways discovered during the planning study
  - The state inspectors determined that all procedures were followed and the corrective actions implemented were acceptable

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ wrong site [230329]
  - Patient prescribed 1.41 GBq (38 mCi), received 63 Gy (6300 rad)
  - Post-treatment imaging determined that some activity was taken up by unintended segments of the liver
  - The procedure was determined to be performed correctly but the activity was transferred due to the complex hepatic flow
  - No adverse effects are expected
  - The licensee indicated that the procedure was performed successfully and that this is an expected risk of the procedure, therefore no corrective actions can be taken
  - This event is still under review

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230326]
  - Patient prescribed 0.98 GBq (26.4 mCi), received 0.77 GBq (20.7 mCi)
  - Treatment was performed without incident
  - Post-treatment surveys discovered a significant number of microspheres remaining in the source vial
  - The dose administered was determined to be clinically sufficient
  - Root cause was unable to be determined, the licensee plans to return the device to the manufacturer for examination

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230322]
  - Patient prescribed 1.08 GBq (29.18 mCi), received 0.784 GBq (21.18 mCi)
  - Treatment occurred without incident, but post-treatment surveys revealed microspheres in the waste vial
  - Imaging revealed that microspheres were stuck at the juncture of the outflow tube and the microcatheter
  - No adverse effects are expected
  - Reactive inspection did not identify a clear cause, increase pressure may have been caused by tortuous anatomy or microcatheter issues
  - Procedure was followed correctly, and no problems were indicated during the administration
  - The licensee plans to return the device to the manufacturer for investigation

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230305]
  - Patient prescribed 12,000 cGy (rad), received 9,140 cGy (rad).
  - No indication that anything was wrong during the administration, four saline flushes went into the patient with no problem
  - The treatment was observed by the RSO and a manufacturer representative, and all procedures were followed
  - Post-treatment, microspheres were discovered attached to the bottom portion of the septum, and clumped in the microcatheter that did not cause clogging
  - The licensee plans to send the device to the manufacturer for investigation following decay

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230281]
  - Patient prescribed 539.46 MBq (14.58 mCi), received 36.74 MBq (0.993 mCi)
  - Physician stated that the procedure proceeded normally aside from a little more resistance than usual
  - Subsequent imaging showed little to no activity in the patient, surveys of the waste revealed that the majority of the activity remained in the tubing
  - A specialized catheter for Y-90 administrations (Trinav 130 cm) was used with a 20 cm extension catheter

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230281](cont.)
  - Root cause was determined to be the use of the extension catheter
    - The larger internal diameter of the extension reduced the saline velocity, causing the microspheres to fall out of suspension
  - The patient underwent a repeat procedure without issue
  - Corrective actions included training, no longer using extension tubing, and ordering longer Trinav catheters

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230275]
  - Patient prescribed 753 MBq (20.35 mCi), received 215 MBq (5.81 mCi)
  - Measurement of the vial following treatment showed a significant amount of activity remaining in the vial
  - Root cause is under investigation but is suspected to be due to a kink in the catheter
  - Patient will likely require further treatment
  - The licensee will send the device back to the manufacturer for investigation following decay

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230261]
  - Patient prescribed 2.54 GBq (68.5 mCi), received 0.13 GBq (3.6 mCi)
  - Post-treatment surveys discovered microspheres blocked in a tubing connector
  - No spillage or contamination was identified
  - Investigation is ongoing

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230230]
  - Patient prescribed 518 MBq (14 mCi), received 31.45 MBq (0.85 mCi)
  - Obstruction was noticed early during the treatment
  - Administration was halted following the discovery of the obstruction
  - A similar event has occurred at this licensee regarding Y-90 devices from the same batch
  - All microsphere administrations from that batch have been paused
  - Investigation is ongoing

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230221]
  - Patient prescribed 742.22 MBq (20.06 mCi), received 34.41 MBq (0.93 mCi)
  - Obstruction was noticed early during the treatment
  - Administration was halted following the discovery of the obstruction
  - A similar event has occurred at this licensee regarding Y-90 devices from the same batch
  - All microsphere administrations from that batch have been paused
  - Investigation is ongoing

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230211]
  - Patient prescribed 1.03 GBq (27.72 mCi), received 0.64 GBq (17.38 mCi)
  - During treatment a 2.4 French TriNav anti-reflux catheter was attached to the delivery device
  - No microspheres were found in the tubing or delivery system post-treatment
  - Surveys of the catheters found high residual activity remaining
  - Post-treatment scans revealed activity in the left hepaitic lobe with unusual uptake in the spleen/gastric region

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230211](cont.)
  - Root cause is suspected to be a microcatheter rupture during administration, resulting in high residual activity in the catheter and unusual distribution
  - Patient was admitted for observation and remained asymptomatic
  - Corrective actions included discontinuing use of the anti-reflux catheters and retraining

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230193]
  - Patient prescribed 1.282 GBq (34.7 mCi), received 0.981 GBq (26.5 mCi)
  - Post-treatment imaging revealed microspheres remaining in the delivery kit tubing
  - Root cause was determined to be human error
    - The AU could not recall if the microcatheter connection had been placed in the holder on the extension arm
    - The dosimeter did not detect microspheres moving through the tubing
  - No adverse effects are expected
  - Corrective actions included reminders of best practices during a Y-90 treatment and additional surveys of the tubing for verification that microspheres have moved through during the treatment

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ wrong site [230101]
  - Patient prescribed 0.8 GBq (21.62 mCi) for one liver segment and 1.93 GBq (52.16 mCi) for another, these doses were switched during the administration
  - The physician asked for the first dose but was brought the second dose
  - After verbally reading the dose, the vial was connected and delivered
  - Root cause was determined to be human error
  - Corrective actions included a radiation dosing education program with event background and call back procedures, as well as additional training for personnel

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230029]
  - Patient prescribed 1.377 GBq (37.22 mCi), received 0.451 GBq (12.19 mCi)
  - Treatment was administered according to manufacturer requirements with no errors
  - During the second saline flush a technologist noticed that liquid was pooling inside the acrylic pot inside the lead pig
  - Multiple attempts to stop the pooling were unsuccessful and the administration was halted

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230029](cont.)
  - Surveying of the waste container gave an estimate of the activity actually administered
  - The patient will be evaluated at follow up for future treatment
  - No root cause was able to be identified
  - No specific corrective actions were implemented
  - The administration kit will be returned to the manufacturer for analysis after decay

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ wrong site [220509]
  - Patient prescribed 666 MBq (18 mCi) to segment 5 of the liver, received 520 MBq (14.05 mCi) to segments 7 and 8
  - A stenosis in the target vessel required changing the treatment vessel to the origin of the vessel
  - An unexpectedly large volume of the microsphere refluxed into the wrong segments of the liver
  - No corrective actions were taken

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230021]
  - Patient prescribed 1.377 GBq (37.22 mCi), received 0.903 GBq (24.41 mCi)
  - The licensee suspected low flow rates had caused occlusion I the catheter
  - After analysis by the manufacturer determined that the injector needles were bent at a 90 degree angle and there was a kink in the tubing at the pinch clamp
    - Could not verify if these were problems pre or post-treatment
  - Blood clots and microspheres were also found in the waste collection vial

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [230021](cont.)
  - Root cause was determined to be low flow rate, the cause of which could not be identified
  - No adverse effects are expected and the dose was determined to be medically sufficient
  - Corrective actions included the use of a electronic dosimeter near the patient to identify blockages or buildup of material between the device and the patient

# 35.1000 TheraSphere™

- Y-90 TheraSphere™ wrong site [220433]
  - Patient prescribed 848.4 MBq (23.2 mCi) to left lobe segments 5 and 8, received 847.3 MBq (22.9 mCi) to left lobe segment 4
  - Written directive error, the dose was originally intended to be given to segment 4 but a typographical error resulted in the wrong written directive being produced
  - No effects are expected to the patient
  - Corrective actions included specifying the treated segment in writing with a formal review of the directive by the treating interventional radiologist
  - Additionally, the treatment quality control will include a verbal verification of the treatment site prior to administering the dose

# 35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [230209]
  - Patient prescribed 536.5 MBq (14.5 mCi) and 802.9 MBq (21.7 mCi), received 196.1 MBq (5.3 mCi) and 455.47 MBq (12.31 mCi) respectively
  - Patient prescribed 2 vials of microspheres for the treatment
  - Manufacturer could not find any residual microspheres in the device and testing revealed no errors
  - Root cause was determined to be a leak between the delivery system and the administration catheter
  - Corrective actions included procedure modifications, additional training, and obtaining new equipment

# 35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® overdose [230155]
  - Patient prescribed 1.6 GBq (43.2 mCi) and 0.7 GBq (18.9 mCi), received 2.34 GBq (63.2 mCi) and 0.77 GBq (20.8 mCi)
  - One written directive for a split dose administration, 2 doses for 2 separate locations
  - RSO inadvertently entered the total of both doses into the prescribed dose section of the treatment planning spreadsheet
  - Additionally, only GBq were used, disguising the unexpectedly large dose for the first administration
  - No adverse effects are expected
  - Corrective actions included revision of procedures and the calculation spreadsheet, preparing separate written directives for spilt doses, listing the activity in both GBq and mCi on relevant forms and containers, and creating a no distraction zone in the preparation hot lab

# 35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220404]
  - Patient prescribed 0.407 GBq (11 mCi), received 1.4 GBq (37.9 mCi)
  - Intended to be a two-step successive administration
  - Technologist drew 2.23 GBq (60.3 mCi) for the first step instead of the intended 0.223 GBq (6.03 mCi)
  - Statis administration of this dose was estimated and no further administration to the patient occurred

# 35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220404](cont.)
  - Root cause was determined to be a lack of standardized written NM procedures for microsphere administration verification and inexperience by the administering technologist
  - Corrective actions included formalized staff retraining, rewritten procedures, establishment of a secondary verification during dose preparation, use of a volume determination spreadsheet, and use of a chart of expected measurements for known amounts of activity

# 35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® wrong site [230065]
  - Patient prescribed 1.32 GBq (35.74 mCi) to the right lobe of the liver, received 1.35 GBq (36.48 mCi) to the left lobe of the liver
  - Root cause was determined to be human error
  - No adverse effects are expected, the left lobe of the liver was intended to be treated under a different written directive after this event occurred with a dose within 20% of this administered dose
  - Corrective actions included procedure modifications and additional training
  - The procedure was updated to require verbal verification of the lobe being treated and an additional review by the physician prior to treatment

# 35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [230026]
  - Patient prescribed 53.65 MBq (1.45 mCi), received 19.61 MBq (0.53 mCi)
  - Root cause was determined to be the very small amount of dose attempting to be drawn up (0.07cc)
  - Multiple attempts to draw this dose caused the dose vial to not completely seal
  - AU decided to stop the procedure
  - No adverse effects are expected

# 35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220537]
  - Patient prescribed 700.41 MBq (19.93 mCi), received 557.59 MBq (15.07 mCi)
  - Treatment was delivered without error
  - Further investigation discovered that the procedure had reached stasis
  - Root cause was determined to be failure to identify stasis and lack of sufficient training
  - Corrective actions included additional training

# 35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220521]
  - Patient prescribed 3.39 GBq (91.6 mCi), received 2.02 GBq (54.6 mCi)
  - Did not appear to involve stasis
  - Root cause was determined to be equipment failure
  - Corrective actions included disposal of the involved equipment

# 35.1000 SIR-Spheres®

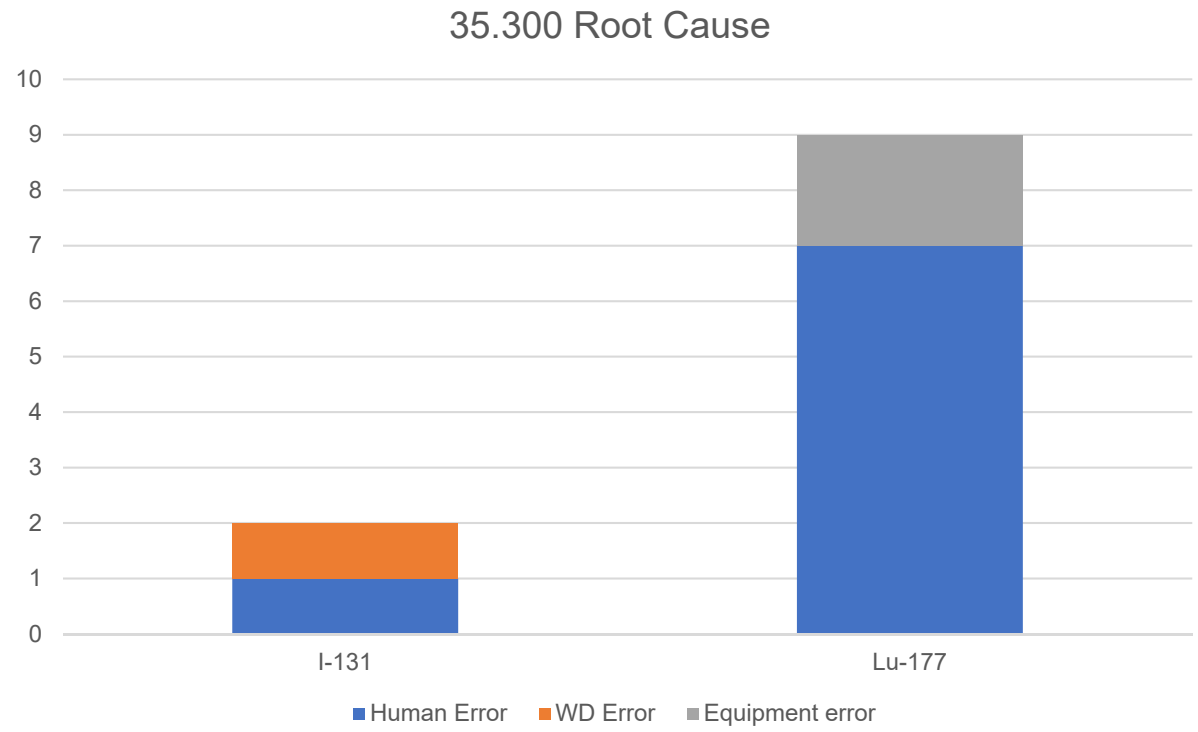
- Y-90 SIR-Spheres® underdose [220505]
  - Patient prescribed 495.8 MBq (13.4 mCi), received 305.62 MBq (8.26 mCi)
  - Procedure occurred without incident, no stasis
  - Post-treatment survey of the tubing found a significant amount of microspheres remaining in the catheter
  - No leakage or contamination was found
  - The procedure was followed correctly and the equipment used was in line with manufacturer recommendations
  - Root cause was suspected by the manufacturer to be a premature air pause
  - Corrective actions included refresher training

# 35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [210474]
  - Patient prescribed 399.6 MBq (10.8 mCi), received 160.2 MBq (4.33 mCi)
  - An appropriately sized catheter was used
  - Vascular access to the treatment site was unusually tortuous
  - Manufacturer representatives observing the treatment noted no deviations from recommended protocols
  - Root cause was suspected to be collection of the microspheres to the catheter walls due to tortuous anatomy or excessive bends in the line
  - Corrective actions are pending

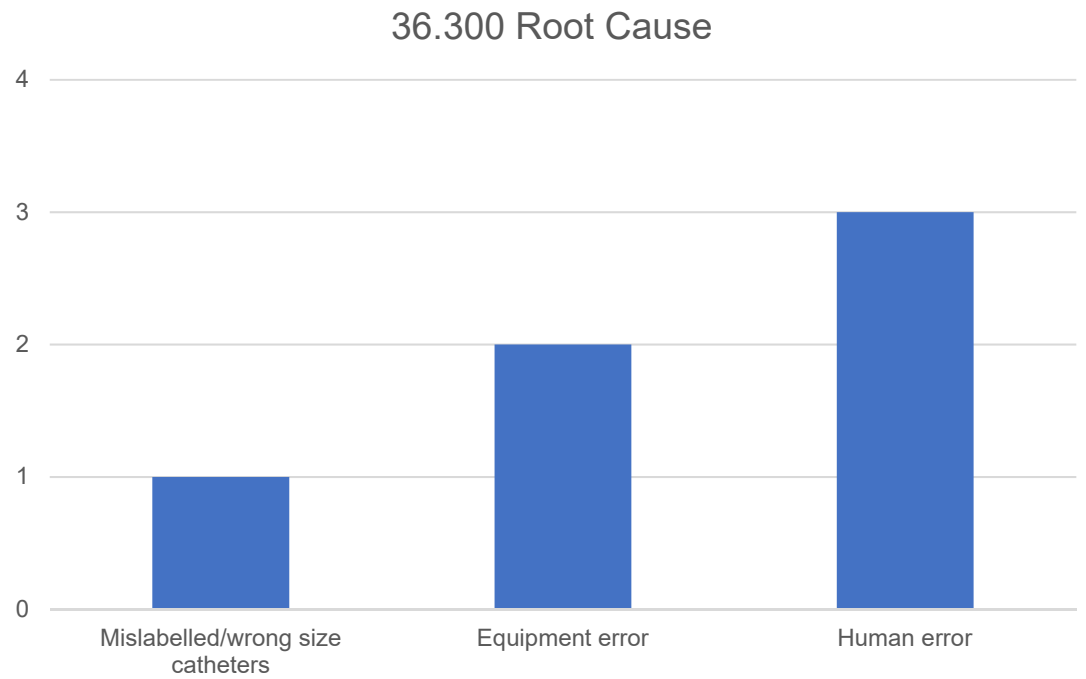
# Summary

- 35.300
  - Primarily Lu-177 events, huma error underdoses
  - Mix-up Lutathera and Pluvicto, mix-ups on patients
  - Supply chain issues for delivery equipment



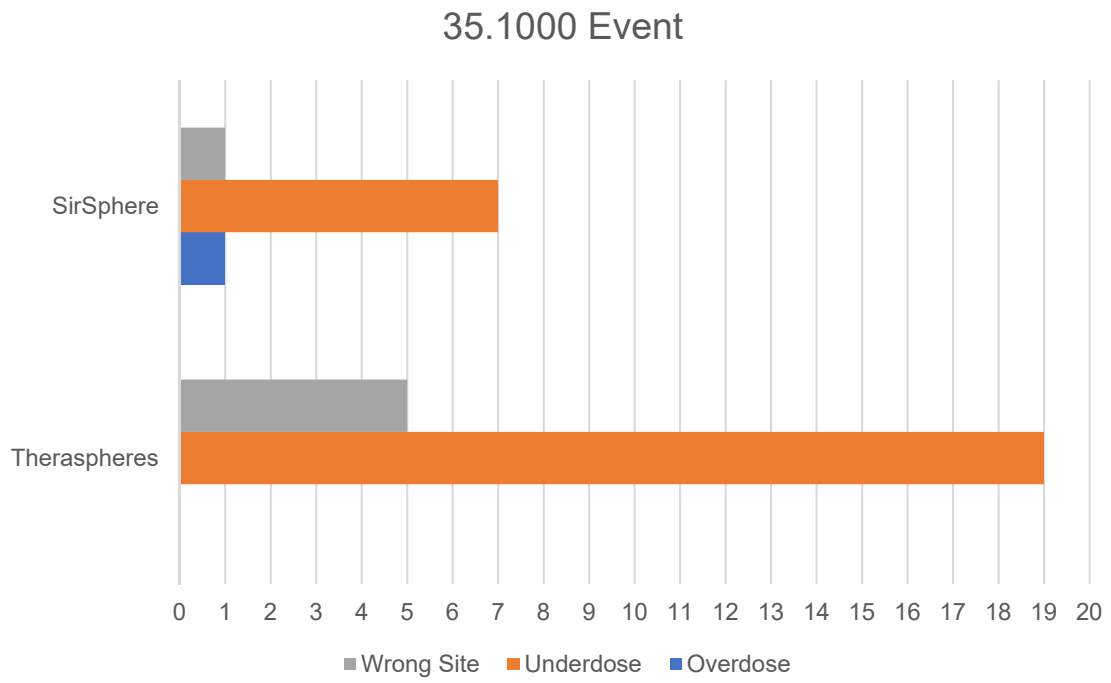
# Summary

- 35.600
  - Primarily human error events, few equipment failures
  - Full dose delivery in one fraction
  - Incorrect anatomical placement



# Summary

- 35.1000
  - Primarily Y-90 Theraspheres, primarily underdoses
  - Collaboration with manufacturers
  - Possible complications with catheter supplements (anti-reflux cage, extension)



# 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?