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

Status of Medical Events FY 2021

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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 2016 - 2018

- **50 Medical events reported - FY 2016**
- **43 Medical events reported - FY 2017**
- **48 Medical events reported - FY 2018**

	FY16	FY17	FY18
35.200	4	0	0
35.300	4	4	2
35.400	6 (18*)	7	11 (13*)
35.600	6	8 (14*)	10
35.1000	30	24	25 (26*)

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

Medical Events FY 2019 - 2021

- **56 Medical events reported - FY 2019**
- **48 Medical events reported - FY 2020**
- **64 Medical events reported - FY 2021**

	FY19	FY20	FY21
35.200	1 (8*)	0	4
35.300	9	2	10
35.400	5	6	4
35.600	9 (10*)	13	5
35.1000	32	27	41

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

Medical Events 2021

35.200 Medical events	**4**
FDG Overdose	1
Wrong radiopharmaceutical	3

35.200 FDG

- Patient overdose
  - Prescribed 0.37 GBq (10 mCi), administered 3.85 GBq (104 mCi)
  - Technician realized he administered the wrong dosage after the treatment

35.200 I-123

- Wrong Drug
  - Prescribed 7.4 MBq (200 μCi) of I-123, administered 5.55 GBq (150 mCi) of I-131
  - Patient called back to the hospital and given KI
  - Stayed at hospital for four days under I-131 safety protocols
  - Planned dose to thyroid was 2.37 cGy (rad)
  - Early estimates of the dose received ranged from 1,220 cGy (rad) to 155,000 cGy (rad)
  - Dose estimates could not accurately account for KI administration
  - Patient lost sense of taste and was given Synthroid medication

35.200 I-123 (cont)

- Root cause determined to be several errors by NMT
  - Appearance and size of I-123 and I-131 capsules are very different
  - The containers are also very different and are kept in separate rooms
  - Patient's name and DOB are visible on outside labels for all doses
  - Doses are checked in a dose calibrator to ensure correct dosage
- All iodine procedures now require two NMTs to sign off before administration
- NMT initial competency will be evaluated between diagnostic and therapeutic doses
- Involved NMT had their employment terminated
- Safety Event Analysis was scheduled to review the incident

35.200 Tc-99m

- Wrong Drug
  - Patient was prescribed 1.11 GBq (30 mCi) of Tc-99m Sestamibi, administered 4.42 GBq (119.49 mCi) of Tc-99m Sodium Pertechnetate
  - Effective dose estimated to be 5.7474 cSv (rem)

35.200 MDP

- Wrong Radiopharmaceutical
  - Anonymous allegation that patient injected with MDP during a stress test
  - The same patient was also injected with Tc-99m Sestamibi at a later time
  - More information has been requested

Medical Events 2021

35.300 Medical events	**10**
Targeted Thorium Therapy	1
Lutetium-177	3
I-131 NaI	3
I-131 Iomab-B	2
Xofigo	1

35.300 Targeted Thorium Therapy

- Wrong Drug
- Prescribed 0.0405 mCi of Th-227 epidermal growth factor receptor 2 (HER-2) Target Thorium Conjugate (TTC), received 0.046 mCi of Th-227 mesothelin (MSLN) TTC
  - Investigative study involving novel TTC intended to deliver radioisotope to HER-2 antigen expressing tumor tissue
  - Incorrectly labelled by manufacturer
  - Both drugs are processed the same in the body
  - Estimated doses are : 609 cGy (rad) to liver, 164 cGy (rad) to small intestine, 174 cGy (rad) to kidneys, and 85.3 cGy (rad) to red marrow
  - No toxicities were noted after six weeks of monitoring

35.300 I-131 NaI

- Patient overdose
  - Patient prescribed 1.11 GBq (30 mCi), received 3.7 GBq (100 mCi)
  - Expected whole body dose of 26.64 cSv (rem) and dose to the bladder wall of 225.7 cGy (rad)
  - Dosage of 3.7 GBq (100 mCi) was verbally given to technologist
  - Did not check written directive prescription of 30 mCi
  - NMT was using a worksheet with the incorrect dosage of 100 mCi
  - Root cause was determined to be human error
  - Corrective actions included new personnel hires, improved supervision, and procedure modifications

35.300 I-131 NaI

- Patient underdose
  - Patient prescribed 7.4 GBq (200mCi), received 2.22 GBq (60 mCi)
  - Dose was divided into two capsules
  - Patient only received one of two capsules
  - Second capsule stuck in shipping vial, discovered by radiopharmacy in the returned vial
  - Subsequent dose was administered to complete thyroid cancer treatment

35.300 I-131 NaI

- Patient underdose
  - Patient prescribed 3.7 GBq (100mCi), received 0.7215 GBq (19.5 mCi)
  - Dose prescribed was 10,000 cGy (rad), dose administered was 3,900 cGy (rad)
  - Patient only received one capsule of a two-capsule treatment
  - Remaining capsule was accounted for in the original vial
  - Root cause determined to be human error, did not follow written handling and survey procedures
  - Procedures were updated for radiotherapy isotope administrations
  - DOT/HAZMAT training and supplementary radiation protection training was administered to all technologists

35.300 Lu-177 Dotatate

- Patient underdose
  - Patient prescribed 7.4 GBq (200 mCi), received 5.06 GBq (136.64 mCi)
  - Leakage in adaptor/needle connection
  - No personnel or area contamination
  - No adverse effects to the patient were expected
  - Root cause determined to be defective part of the assembly, specifically the dual male adaptor
    - » Lack of vacuum seal at the septum from re-puncturing with the new assembly setup was also a contributing factor

35.300 Lu-177 Lutathera

- Patient underdose
  - Patient was prescribed 7.4 GBq (200 mCi) of Lu-177
  - Patient received 1.04 GBq (28 mCi), 14% of prescribed
  - Procedure stopped after the patient stated they had a chemotherapy injection the day before, instead of after the radiopharmaceutical therapy
  - The prescribed dose was 479 cGy (rad) but estimated delivered dose to the kidney was 67 cGy (rad)
  - No medical impact expected
  - Root cause was determined to be inadequate review of patient records by authorized user

35.300 Lu-177 Lutathera

- Patient underdose
  - Patient prescribed 7.4 GBq (200 mCi), received 0.666 GBq (18 mCi)
  - Technician had difficulty establishing IV injection site and flow
  - No adverse effects were noted and none were expected
  - Cause was determined to be poor venous access and incorrect gauge needle

35.300 I-131 Iomab-B

- Patient underdose
  - Prescribed 414.4 MBq (11.2 mCi) (measured at 388.5 MBq (10.5 mCi) prior to administration)
  - Delivered 212.38 MBq (5.74 mCi); 51% of the prescribed dose (residual activity in vial and tubing was 176.12 MBq (4.76 mCi))
  - Considerable air in tubing required replacement of infusion set
  - Problem persisted with the second set of tubing, so the administration was stopped

35.300 I-131 Iomab-B (cont.)

- 38 mL of the 43 mL dosage was administered
- Approximately 0.111 Sv (11.1 rem) difference in prescribed and actual effective dose
- No re-administration of diagnostic dose was required, and the therapy dose was readministered without incident
- Corrective actions included procedure modifications

35.300 I-131 Iomab-B

- Patient underdose
  - Patient prescribed 35.11 GBq (949 mCi), received 18.76 GBq (507 mCi)
  - Dose administered was 1,900 cGy (rad)
  - Leaking tube from infusion system, nurse inadvertently removed a tube occluding clamp and opened the roller clamp on the flush bag line at the beginning of the infusion
  - No adverse effects expected, bone marrow dose was considered to be sufficient
  - Supplemental training was provided to the radiopharmacist and nuclear medicine supervisor on operating and setting up the infusion pump
    - » Solely responsible for setting up and operating the pump for all future patients
  - Checklist developed for pump operation

35.300 Ra-223 Xofigo

- Patient underdose
  - Patient prescribed 3.47MBq (93.65 µCi), received 0.63 MBq (17.1 µCi)
  - Procedure was cancelled due to low blood pressure, dose kept in hot lab for decay
  - New dose ordered, however the decayed, original dose was delivered
  - Patient brought back after the event; remaining dose delivered
  - Administrative actions taken to prevent reoccurrence

Medical Events 2021

35.400 Medical events	**4**
Prostate	3
Mammosite	1

35.400 I-125 Prostate

- Wrong Site
  - Prescribed 1.013 GBq (27.378 mCi), 54 seeds, prescribed dose of 14,500 cGy (rad)
  - Follow-up CT revealed that all seeds were implanted in penile bulb
  - Malfunction of ultrasound ruled out
  - Review indicated that if the foley catheter was not fully visible on images it could result in incorrect implantation
  - Root cause was human error
  - Changes to prostate brachytherapy protocol implemented an additional step to ensure clear identification of prostate gland and surrounding anatomy
  - Follow-up scans from previous cases involving this type of procedure indicated this was not a repeated event

35.400 Cs-131 Prostate

- Wrong site
  - Patient prescribed 7.34 GBq (198.26 mCi), received 1.41 GBq (38.12 mCi)
  - Prostate D90 dose was 26.26% of the prescribed dose
  - Perineal region received a V100 dose of 11,500 cGy (rad)
  - Urethra and rectum received approx. 50% of expected dose
  - Plan to insert stranded seeds around the prostate periphery and individual seeds at the apex, base, and interior of the prostate
  - Ultrasound probe was not accurately advanced on sagittal imaging to see the prostate
  - 63 of 78 stranded seeds were implanted in the perineum below the prostate, 15 loose seeds were implanted in the prostate

35.400 Cs-131 Prostate (cont.)

- Corrective actions included frame of reference establishing using the stepper position to identify base and apex of prostate
- During the procedure, a timeout will be performed to identify both the prostate and the bladder
- Retraining program was planned to include retraining and proctoring by a qualified radiation oncology physician and physicist
- External beam radiotherapy was performed to boost treatment to areas that received less dose
- Patient was scheduled for long-term follow-up

35.400 I-125 Prostate

- Patient Overdose
  - Patient prescribed 845.38 MBq (22.848 mCi) total activity for 64 prostate brachytherapy seeds
  - Authorized user discovered a mistake when entering the source strength into the treatment planning system
  - Inadvertently entered the seed strength of 13.21 MBq (0.357 mCi) into the air-kerma strength field
  - Prescribed dose was 110,000 cGy (rad), delivered dose was 140,000 cGy (rad)
  - No negative effects were expected, start of a two-part treatment plan
    - » Second part was a linear accelerator treatment, which was adjusted to accommodate the overdose
  - Corrective actions included procedure revision

35.400 Mammosite

- Wrong Patient
  - Wrong patient received breast cancer treatment
  - Determined not to be medical event in 2001, reevaluated after inspection
  - No details of the event were saved except that the patient dose exceeded 5 cSv (rem) EDE, or 50 cSv (rem) to an organ or tissue, or 50 cSv (rem) SDE to the skin
  - No related records could be obtained, past record retention period

Medical Events 2021

35.600 Medical events	**5**
Gynecological	4
Skin	1

35.600 HDR

- Patient overdose
- 216.56 GBq (5.853 Ci) Ir-192 HDR unit
- Patient prescribed 5000 cGy (rad) in 20 fractions at 250 cGy (rad) per fraction
  - Treatment for skin cancer using 35mm cone
  - Treatment occurred at correct site but without the 35mm cone for one fraction
  - Unintended skin dose was approx. 70 cGy (rad) above expected
- No effects were expected to the patient
- Corrective actions included
  - Advance preparation of treatment room with correct cone sizes
  - Physicist verification of applicator size and treatment site
  - Cone placed on skin and outline drawn by physician or physicist
  - Treatment outline and placement of applicator re confirmed before treatment is administered

35.600 HDR

- Wrong site
- Patient was treated with fraction 2 of 3 with a vaginal cylinder
  - After treatment, the physician noted that the cylinder had been displaced 6 cm
  - Exact cause was unknown but could have been due to patient movement or loosening of the cylinder holder
  - Estimated dose difference of approximately 558 cGy (rad)
  - Patient did not experience any irregular toxicities
  - Corrective actions included removing the device from service

35.600 Ir-192 HDR

- Wrong site
- Patient being treated with a 190.04 GBq (5.14 Ci) Ir-192 source
  - Source transfer tube was 12 cm too long, maximum shallow dose of 800 to 900 cGy (rad) to vagina
  - Root cause was determined to be failure of medical staff to follow established procedures
  - Also a failure to identify a difference in planned and measured transfer tube lengths
- No adverse health effects are expected

35.600 Ir-192 HDR (cont.)

- Corrective actions included addition of expected lengths of different channels in the HDR pre-treatment delivery checklist
- Also added measured length with the source position check ruler for each channel to checklist, to be completed and signed off on by the treating RTT prior to physicist review for all HDR cases
- Checklist approved by physicist prior to treatment to allow enough time for physician to verify accuracy

35.600 HDR

- Wrong site
- 256.41 GBq (6.93 Ci) Ir-192 HDR unit
- Patient prescribed five fractions of 600 cGy (rad) during an HDR gynecological treatment
  - After the third treatment, it was determined that a 125 cm transfer tube was used instead of the expected 113 cm transfer tube
  - Dose was delivered 12 cm away from expected site
  - Exposed tissue was largely fatty tissue, max dose to any tissue was 600 cGy (rad)
  - Authorized medical physicist did not identify the correct tube length during the verification process
- Corrective actions included removal of all 113 cm transfer tubes, only 125 cm tubes will be used for all future treatments
- All physicists were reminded of mandatory checks before all treatments and re-educated on procedural process

35.600 HDR

- Underdose
- 462.87 GBq (12.51 Ci) HDR unit
- Patient prescribed single 700 cGy (rad) fraction, received 525 cGy (rad)
  - Sometime during planning process dose scalar was adjusted by 25%
  - Most likely occurred when user was rotating/panning through images
  - Root cause was determined to be human error
- No adverse effects are expected
- Corrective actions included modifying procedures to include an additional step in the pre-check procedure to verify the correct dose and dwell times
- Training was also conducted on the incident and procedure changes with all staff and users

Medical Events 2021

35.1000 Medical events	**41**
Y-90 Microspheres	
– TheraSphere™	31
– SIR-Spheres®	10

35.1000 TheraSphere™

- Y-90 TheraSphere™ wrong location
  - Patient prescribed 2.55 GBq (68.92 mCi) to the left lobe, received 2.48 GBq (66.96 mCi) to right lobe
  - Catheter placement was verified prior to treatment by angiography and fluoroscopy
  - AU believes the catheter was kicked out during treatment, but no definitive cause was determined
- No adverse effects were expected
- Corrective actions included a new written procedure

35.1000 TheraSphere™

- Y-90 TheraSphere™ overdose
  - Patient prescribed 3.841 GBq (103.8 mCi), received 4.751 GBq (128.4 mCi)
  - Event was discovered by the RSO after a records review
  - Dose was calibrated for administration the day after the administration took place
    - Resulting activity was higher at administration
  - Root cause was determined to be human error
  - Corrective actions included secondary review of written directive, addition of another pre-administration form, and updated procedures

35.1000 TheraSphere™

- Y-90 TheraSphere™ overdose
  - Patient prescribed 1.75 GBq (47.3 mCi), received 2.224 GBq (60.11 mCi)
  - Event discovered after treatment by RSO during a review of therapies
  - Dose was administered a day too early, calibrated for the day after

35.1000 TheraSphere™

- Y-90 TheraSphere™ overdose (cont.)
  - Several corrective actions were taken
    - Operating procedures were revised to clarify responsibilities of involved participants
    - Dose will not be ordered until a microsphere treatment window illustrator is received, a complete written directive is received, there are no discrepancies between to two, NM verifies that the written directive is complete, and NM confirms the dose is appropriate for the date and time of administration
    - Second verification after receipt of dose
    - Time-out process was formalized
    - NM staff and AUs were trained on the changes
    - All AUs received a memo reminding them of their reporting responsibility
    - Office of Radiation Safety continued quarterly audits
    - Refresher training was performed

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 1.73 GBq (46.7 mCi), received 0.9324 GBq (25.2 mCi)
  - During treatment the physician noted that microspheres were visibly clogged in the catheter, discontinued the administration
  - Physician requested a larger catheter but was only able to find a smaller catheter
    - Noted the full dose might not be able to be delivered but elected to continue
  - Manufacturer review of the equipment found microspheres throughout the device and high back pressure and low flow rate
  - No adverse effects were expected, and follow-up treatment was successfully delivered

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 72,000 cGy (rad), received 36,620 cGy (rad)
  - Remaining microspheres remained in microsphere kit
  - Physician stated the patient received an adequate therapeutic dose

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 1.23 GBq (mCi), received 0.88 GBq (mCi)
  - No personnel or area contamination was noted
  - Leaky connections ruled out and no root cause was determined
  - Later inspections showed that the microspheres likely clumped in the vial
    - Saline was administered successfully, and scans showed bulk of material remained in the vial
  - May be due to inadequate tilting of the vial, tapping on a firm surface, or not taking those actions immediately prior to administration

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 12,000 cGy (rad), received 9,200 cGy (rad)
  - No personnel or area contamination was noted
  - Suspected kink in delivery system
  - Later inspection determined the root cause to be tortuous anatomy of the patient
  - The patient was also receiving chemotherapy treatment simultaneously, which was not recommended by the vendor representative
  - No corrective actions were taken

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 4.05 GBq (109.5 mCi) to liver lobes 5 and 8, 5.66 GBq (153 mCi) to lobes 6 and 7
  - Patient only received 2.53 GBq (68.5 mCi) to lobes 6 and 7
  - Blockage occurred in the microcatheter, unable to be cleared
  - Post procedure survey indicated residual activity in the microcatheter
  - Microcatheter used (d = 0.49mm) was smaller than recommended size (d = 0.5mm)
  - Corrective actions included using a larger catheter for subsequent treatment

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 547.6 MBq (14.8 mCi), received 344.84 MBq (9.32 mCi)
  - No adverse effects expected, likely the tumor was adequately treated
  - Investigation identified possible kink in microcatheter as root cause
  - Corrective actions included additional checks for kinks in catheters and tubing

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 2.876 GBq (77.73 mCi), received 1.34 GBq (36.22 mCi)
    - Also 0.027 GBq (0.73 mCi) to lungs
  - Prior to treatment saline flush had slight resistance but all the flush went through
  - Pressure increased appreciably during the procedure and administration was stopped
  - Post-treatment survey of the catheter indicated greater than normal radioactivity
  - Cause determined to be kink in catheter, but AU stated the treatment area was tortuous
  - No corrective actions taken because proper procedures were followed

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 1.14 GBq (30.8 mCi), received 0.8094 GBq (21.868 mCi)
  - Mechanical blockage occurred in the delivery system
  - All material contained in delivery system, lines, and patient
  - Post treatment imaging indicated activity in the vial
  - No adverse effects were anticipated

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 1.067 GBq (28.84 mCi), received 0.522 GBq (14.11 mCi)
  - Microsphere vial was empty, likely held up in microcatheter
  - AU also believed that the high residual waste reading was due to a slower infusion of treatment dose and flushing saline
  - Normal flow rate was not able to be attained due to small patient vasculature
  - Investigation determined the delivery set worked as intended

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 2.31 GBq (62.43 mCi), received 1.572 GBq (42.49 mCi)
  - Microsphere vial was empty, likely held up in microcatheter
  - Needed more saline flushes than normal to complete procedure (4 vs. 1-2)
  - Microsphere apparatus was new, first-time use
  - Manufacturer issued a product advisory concerning a possible leak point near catheter connection

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 2 doses of 2.4 GBq (64.86 mCi), received 1.067 GBq (28.84 mCi) and 2.374 GBq (64.16 mCi)
  - During first administration the AU noticed leakage from the microcatheter and stopped the infusion to check the connection
  - Continued with the procedure and performed surveys around the room
  - Contamination was found on their hands, performed decontamination procedures and continued with second dose
  - Second dose delivered without incident

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose (cont.)
  - RSO contacted to ensure containment of radioactive material
  - Personnel were surveyed and access to the room was restricted in order to decontaminate
  - Decontamination of room proceeded without incident

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 1.067 GBq (28.86 mCi), received 0.799 GBq (21.62 mCi)
  - Pinch clamp remained online during infusion, discovered after AU noticed more pressure when pushing syringe
  - Clamp removed and treatment resumed
  - Flushed five times to ensure no microspheres remained in tubing
  - Images of the waste container indicated microspheres in inlet and outlet lines
  - AU believes the patient was delivered a clinically effective dose

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose (cont.)
  - Root cause was determined to be failure to follow procedures
    - Checklist was not followed to remove clamp prior to treatment
  - Corrective actions included procedure modification

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 2.46 GBq (66.36 mCi), received 0.47 GBq (12.8 mCi)
  - Microspheres became visually clumped in tubing distal to the box prior to microcatheter connection
  - Multiple saline flushes were not effective in clearing the clump
  - Infusion was stopped after 33 minutes
  - Measurement of the tubing and microcatheter indicated only 20% of dose was delivered to the patient

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 2.95 GBq (79.73 mCi), received 1.15 GBq (31.08 mCi)
  - During treatment, the dosimeter used to measure the spheres remaining in the container indicated a lower than expected rate of decrease in microspheres remaining in the container
  - The device and tubing were flushed more times than normal to remove any residual activity
  - Post-treatment surveys indicated the remaining activity remained in tubing
  - Suspected blockage in the tubing due to small portion of the septum lodged in needle after being pierced

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 2 doses of 0.79 GBq (21.35 mCi) to left lobe segments 4A and 4B, received 0.465 and 0.594 GBq (12.57 and 16.05 mCi) to segments 4A and 4B
  - Radiation surveys of the vials post treatment revealed that some microspheres adhered to the tubing
  - Standard protocol was followed yet no root cause was identified during discussions with the manufacturer
    - Flushing with saline 3 times
  - Known risk that microspheres can be stuck in device in rare occasions

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 640.1 MBq (17.3 mCi), received 401.82 MBq (10.86 mCi)
  - Root cause was leakage of microspheres at the connection between tubing and microcatheter
  - Leakage resulted in personnel and area contamination
  - Addressed by Radiation Safety staff, no skin effects were reported or expected
  - No adverse effects to the patient
  - Corrective actions included procedure modifications

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 1.33 GBq (35.9 mCi), received 0.75 GBq (20.2 mCi)
  - Two doses were prepared for two separate sites of the liver
  - Doses were correctly labeled and prepared, but the smaller dose was administered to the site that needed the higher dose
  - The second dose was not administered
  - Root cause was determined to be miscommunication between NMT and AU

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose (cont.)
  - No adverse effects occurred, and the dose was determined to be clinically effective
  - Corrective actions included updates to the administration checklist, discussion of the use of a “closed loop” communication between the administrator of the dose and the physician requesting the dose, and increased training for applicable personnel

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 888 MBq (24 mCi), received less than 710.4 MBq (19.2 mCi)
  - A significant amount of microspheres leaked out of the tubing/catheter connection during the procedure
  - Sterile, non-radioactive solution was able to be pushed through the tubing without incident
  - Several drops were noticed at the connection during the administration and were cleaned off
  - Contamination was detected on the gloves, patient's drape, and towels after the treatment
  - No contamination was detected on the floor, patient, or staff

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose (cont.)
  - Imaging indicated radioactivity in the patient's liver
  - No adverse effects were expected
  - Physician stated connecting the catheters took more force than normal, indicating a possible defect
  - Corrective actions included update procedures so two people check the connection between catheters
  - The procedure was repeated at a later date to accomplish the prescribed dose

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 828 MBq (22.379 mCi), received 624 MBq (16.865 mCi)
  - No contamination was detected in the room or on staff members
  - No issues were found with the delivery system or setup
  - No unusual resistance was felt on the syringe during treatment
  - On the day of the treatment an angiogram demonstrated brisk arterial supply to the tumor and verified catheter position
  - No cause was identified
  - No adverse effects were expected

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 688.2 MBq (18.6 mCi), received 144.5 MBq (3.9 mCi)
  - Patient received 21% less dose than prescribed
  - Residual activity remained in delivery system

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 2.36 GBq (63.7 mCi), received 0.074 GBq (2 mCi)
  - Connection between delivery apparatus and catheter failed when the injection started
  - All contamination was contained in the pads below the connection
  - No adverse effects were expected

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose (cont.)
  - Inspection revealed a manufacturing defect in the administration kit
    - Leakage at the Leur outlet
  - Product advisory was issued, and all kits associated with the involved lot numbers were disposed of
  - Corrective actions included staff training

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 2.76 GBq (74.46 mCi), received 1.32 GBq (35.6 mCi)
  - Microcatheter disconnected from the Luer lock during injection
  - Lock was tightened and treatment was completed
  - Leaked microspheres were contained in absorbent towels
  - Underdose was estimated from measurement of tubing, towels, and microcatheter
  - Patient was scheduled for imaging to determine if follow-up treatment was necessary
  - Corrective actions included checklist training, with a focus on the Luer lock connection

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 860 MBq (23.24 mCi), received 359.738 MBq (9.72 mCi)
  - Patient prescribed same dose to four lobes of liver
  - Three lobes received correct dose; one was underdosed
  - Analysis of the delivery kit found residual microspheres in the last few inches of tubing, in the microcatheter hub, and in the initial length of the microcatheter
  - Indication of obstruction downstream of administration set
  - Catheter was in good condition but only a limited flow rate could be achieved

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose (cont.)
  - Microcatheter did not meet size requirements for TheraSphere™ administration
  - No adverse effects were expected
  - Follow-up imaging determined the treatment was clinically effective
  - Corrective actions included use of correct microcatheters, and notification of physicians of the correct microcatheter to use

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 1.79 GBq (48.38 mCi), received 0.716 GBq (19.35 mCi)
  - Root cause was not clear but likely due to selection of a distal arterial branch for administration
  - 3 hairpin turns may have resulted in “ovalization” of the microcatheter lumen
  - Location was checked multiple times during treatment and flow was established with saline and contrast
  - Ovalization may have resulted in greater pressure on administration set
  - Corrective actions included cessation of treatment on patients with a significant number of tight turns

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 592 MBq (16 mCi), received 368 MBq (9.95 mCi)
  - Leak was identified between administration kit and microcatheter
  - Spill was confined to patient drape, confirmed by follow-up surveys of the room and staff
  - Root cause was determined to be mismatch between the administration set received from manufacturer and previous kits used, resulting in a leaky junction

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 594.94 MBq (16.08 mCi), received 270.1 MBq (7.3 mCi)
  - Treatment appeared to be correct, survey of items used determined the patient had been underdosed
  - Experiments to find the root cause determined that if the connection between the delivery set and the microcatheter was not vertically oriented, the microspheres would become stuck
  - These findings were communicated to all AUs
  - Corrective actions included amending checklist to specify that the connection must be oriented vertically
  - Patient will be followed to determine if further treatment is needed

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 1.56 GBq (42.24 mCi), received 1.04 GBq (28.1 mCi)
  - Treatment appeared to be correct, survey of catheter indicated higher than normal residual activity
  - Experiments to find the root cause determined that if the connection between the delivery set and the microcatheter was not vertically oriented, the microspheres would become stuck
  - These findings were communicated to all AUs
  - Corrective actions included amending checklist to specify that the connection must be oriented vertically
  - Patient will be followed to determine if further treatment is needed

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose
  - Patient prescribed 13.65 GBq (368.92 mCi), received 10.51 GBq (284.07 mCi)
  - Patient received 77% of expected dose, which was determined to be medically appropriate
  - No spill or contamination was detected after surveys
  - Root cause was decay of dose due to multiple treatment reschedules
  - The healthcare center has implemented a program to review accuracy prior to patient scheduling and dose ordered

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® wrong site
  - Patient prescribed 0.29 – 0.83 GBq (7.84 – 22.43 mCi) to left lobe of liver
    - The activity was a range because treatment would be stopped if the left lobe became saturated
  - Post treatment survey indicated the right lobe had received between 33% and 67% of the dose intended for the left lobe
    - Treatment was not intended for the right lobe (patient had been treated for the right lobe previously)
  - Periodic flushing and fluoroscopy was performed and indicated the catheter had moved during the treatment
  - Suspected respiratory motion and vascular pulsations moved the catheter to the right branch
  - No adverse effects were anticipated

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® overdose
  - Patient prescribed 489.14 MBq (13.22 mCi), received 1,168.09 MBq (31.57 mCi)
  - Two different treatments were prepared for different lobes of the liver
  - Higher dose was administered to the wrong lobe
  - Error discovered after treatment of the first lobe
  - The other lobe was correctly treated
  - Root cause was determined to be incorrect labelling and failure to compare dosage to written directive

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® overdose (cont.)
  - Corrective actions included revised procedure that specifies labelling to only include patient initials, radionuclide, activity, and date
  - A time-out was also incorporated to compare each dose to the written directive, signed by the AU

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose
  - Prescribed 13,000 cGy (rad) to lobes 2,3 and another 13,000 cGy (rad) to lobes 4,5
  - Complex vascular flow pattern complicated the treatment delivery
  - Microspheres intended for lobe 2,3 went to segment 4
  - Dose intended for lobes 4 and 5 only went to lobe 5
  - Segment 4 received a dose of 2,500 cGy (rad), and segemtn 5 received a dose of 13,500 cGy (rad)
  - Root cause determined to be incorrect placement of delivery catheter
  - Corrective actions included a review by a quality control committee

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose
  - Patient prescribed 599.4 MBq (mCi), received 140.6 MBq (mCi)
  - During treatment a microcatheter almost immediately clogged
  - No adverse effects were expected
  - Root cause was determined to be clogs in the microcatheter
  - Imaging of the delivery system determined the potential clumping was in the delivery box or the microcatheter

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose
  - Patient prescribed 2.697 GBq (72.9 mCi), received 0.93 GBq (25.16 mCi)
  - No contamination was reported
  - Delivered dose was clinically effective
  - No changes to the catheter or procedures during this administration from prior administrations
  - Root cause was determined to be a clog in the catheter
  - Corrective actions taken included procedure modifications

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose
  - Patient prescribed 3.5 GBq (94.6 mCi), received 2.66 GBq (71.9 mCi)
  - Catheter clogged due to high volume of microspheres
  - Catheter was replaced and no stasis was observed, treatment continued
  - No adverse effects on patient, no additional treatment was required

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose
  - Patient prescribed 1.6 GBq (43.2 mCi), received 0.17 GBq (4.53 mCi)
  - Procedure was stopped after encountering resistance, intended to complete administration at a later time
  - AU disconnected the line before releasing pressure
  - Microspheres were expelled onto administration table and floor covering
  - All coverings were disposed of and the room was decontaminated
  - Root cause was suspected to be clogged microcatheter
  - No adverse effects to the patient, follow-up treatment was administered

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose
  - Patient prescribed 299.7 MBq (8.1 mCi), received 229.4 MBq (6.2 mCi)
  - Root cause was determined to be retention of microspheres in delivery device
  - The relatively large percentage of activity retained in the delivery apparatus may be related to the small activity and volume prescribed
  - No adverse effects were expected; the procedure was expected to be clinically effective
  - Corrective actions included drawing low activity doses (555 MBq [15mCi] or less) using a delivery fraction of 0.90 instead of 0.095
    - Better accommodate the larger residual percentages observed for low activities

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose
  - Patient prescribed 3.6 GBq (97.3 mCi), received 2.46 GBq (66.5 mCi)
  - Full dose was separated into 2 administrations through 2 arteries
  - First administered successfully, second encountered catheter occlusion
  - Root cause was determined to be a deformed catheter with a significant kink point on the inner catheter body
    - Reduced flow rate and allowed for full occlusion of the proximal segment of the catheter

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose (cont.)
  - No adverse effects were expected
  - Patient returned for remainder of the dose at a later time

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose
  - Patient prescribed 1.1174 GBq (30.2 mCi), received 0.8854 GBq (23.93 mCi)
  - NMT encountered increasing resistance during treatment, leading them to believe stasis had been achieved
  - Root cause was a clogged microcatheter discovered post treatment
  - Subsequent treatment was given to make up for underdose
  - Corrective actions included obtaining new equipment

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 technologist
- RSO – radiation safety officer
- SI units – International System of Units
- Y-90 – Yttrium-90

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QUESTIONS?