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

Status of Medical Events FY 2020

Said Daibes Figueroa, Ph.D.
Medical Radiation Safety Team
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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.

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Medical Events FY 2015 - 2017

- **57 Medical events reported - FY 2015**
- **50 Medical events reported - FY 2016**
- **43 Medical events reported - FY 2017**

	FY15	FY16	FY17
35.200	3	4	0
35.300	8	4	4
35.400	9 (10*)	6 (18)	7
35.600	17	6	8 (14)
35.1000	20 (30)	30	24

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

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Medical Events FY 2018 - 2020

- **48 Medical events reported - FY 2018**
- **56 Medical events reported - FY 2019**
- **48 Medical events reported - FY 2020**

	FY18	FY19	FY20
35.200	0	1 (8)	0
35.300	2	9	2
35.400	11 (13)	5	6
35.600	10	9 (10)	13
35.1000	25 (26)	32	27

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Medical Events 2020

35.200 Medical events **0**

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Medical Events 2020

35.300 Medical events **2**

Lutetium-177 2

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35.300 Lu-177 Lutathera

Item Number: 200062

Lu-177 Lutathera **1**

Failure to start amino acid infusion

Patient's kidneys received more dose than intended during treatment for pancreatic cancer.

- Prescribed activity of 7.4 GBq (200 mCi) and received 7.47 GBq (202 mCi).
- Amino acid infusion was initiated 20 minutes late after infusion of Lu-177-Lutathera was started.
- As a result of the error, the kidneys received an estimated dose of 7.4 Gy (740 rad), not the intended 4.9 Gy (490 rad).

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Failure to start amino acid infusion (cont.)

- Amino acid infusion was not initiate because the secondary IV line connected to the fluid bag remained clamped.
- The nurse did not notice the amino acid line was still clamped.
- A primary clamped IV line would have resulted in an alarm.
- Failure to observe the amino acid line was not dripping as required in their protocol
- Corrective Actions:
  - Included switching the fluid bag containing the amino acid solution to a separate primary IV line, which will result in an alarm when the line is clamped.
  - Technologist will take a formal pause with nursing staff prior to administration to ensure that the amino acid infusion has begun prior to Lutathera administration.

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35.300 Leaking Foley Catheter

Item Number: 190569

Lu-177 Lutathera **2**

Leaking Foley Catheter

Patient received a skin injury.

- During infusion, the catheter leak was identified, and decontamination procedures were performed.
- The patient was instructed that there was a chance for skin injury.
- Estimated skin dose was 7 Gy (700 rad).
- Patient informed there was skin irritation in the peri-gluteal and peri-labia areas consistent with radiation injury.
- Corrective Actions: Retraining applicable staff members and modifying the Lu-177 infusion method.

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Medical Events 2020

35.400 Medical events 6

Prostate 4

- Wrong site 2
- Wrong source 1
- Wrong activity 1

Eye Plaque 2

– Overdose 1

– Under dose 1

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35.400 Medical Events

Item Number: 200056

Prostate: Wrong Site 1

- All 76 I-125 brachytherapy seeds were implanted into the bladder instead of the prostate.
  - Each seed contained activity of 12.95 MBq (350 µCi).
- Prescribed dose was 14,500 cGy (rad), using a total I-125 activity of 984.2 MBq (26.6 mCi).
- CT scan identified 41 seeds in the bladder wall.
- No seeds identified in the prostate, urethra, lungs, or other organs.

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35.400 Wrong Site (cont.)

- 35 seeds were urinated out into septic tank system.
- Planned dose to the bladder was 7,500 cGy (rad). Preliminary calculations indicated the post-implant dose volume was 21,000 cGy (rad) to 2 cc of the bladder wall.
- Prostate base location coordinate may have inadvertently shifted or been misidentified.
- The patient experienced urinary frequency, urgency, and nocturia. The patient's potential long-term effect is hemorrhagic cystitis.
- Since fluoroscopy was not used to compare with the ultrasound image, the incorrect location would not have been identified.

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35.400 Wrong Site (cont.)

- Clinic temporarily suspended its prostate seed implant program and performed an internal review.
- The cause was failure to follow established procedures.

- Corrective Actions:
  - Included updating the prostate implant program
  - Performing appropriate training

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35.400 Wrong Site

Item Number: 190555
Prostate: Wrong Site 2
The patient was prescribed to receive 11,000 cGy (rad), but only received 6,820 cGy (rad).

- Two strands of seeds (with two seeds per strand)
- Implanted outside of the prostate towards the rectum
- 96 Cs-131 seeds
- 38% underdose
- Activity of 104.377 MBq (2.821 mCi)
- Seed pattern shifted posteriorly from the pre-plan

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35.400 Wrong Site (cont.)

- SpaceOAR hydrogel was used to minimize dose to the rectum and adverse health effects are not expected to the rectum.
- Cause: human error
- Patient received external beam radiation to make up for the prostate under dosing.

- Corrective Actions:
  - Included generating a new procedure and providing additional training to personnel.

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35.400 Wrong Source

Item Number: 190525
Prostate: Wrong Source 1

Incorrect Cs-131 prostate brachytherapy seed set brought to the operating room

- The patient was prescribed 47 I-125 seeds with a total activity of 116 MBq (3.135 mCi) for a dose of 8,500 cGy (rad).
- Six Incorrect prostate seeds (Cs-131) were implanted.
- Procedure was stopped
- The correct seeds were then implanted
- The patient was administered 112.11 MBq (3.03 mCi).

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35.400 Wrong Source (cont.)

- The patient was prescribed to receive 8,500 cGy (rad) and also received 8,500 cGy (rad).
- No harm is expected to the patient.
- Cause of the incident was determined to be human error.
- Corrective Actions:
  - Included procedure modification and staff refresher training.

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35.400 Wrong Total Activity

Item Number: 190611
Prostate: Wrong total activity **1**

Patient received 8,174 cGy (rad) to the prostate's GTV and the prescribed dose was 12,000 cGy (rad), resulting in a 32% underdose.

- Patient was implanted with fewer seeds than intended.
- 50 I-125 brachytherapy seeds.
- Each seed contained an activity of between 14.28 and 15.43 MBq (386 and 417 µCi).

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35.400 Wrong Total Activity (cont.)

- After implanting 30 seeds, the two applicators suffered jams that could not be cleared.
- Treatment was terminated.
- Applicators had been dormant without manufacturer service for over 12 months.

- Corrective Actions:
  - Included having the manufacturer service all applicators and provide applicator training to all AU and sterilization teams.

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35.400 Wrong Dose

Item Number: 200249
Eye Plaque: Overdose 1

- Patient was prescribed a dose of 8,500 cGy (rad) and received 12,350 cGy (rad), which is 145.3% of the prescribed dose.
- Four days later, the patient had a stroke and was admitted to a different hospital.
- Patient transferred back to licensee but was not strong enough to endure the procedure for removing the eye plaque.
- The eye plaque was subsequently removed on day 7.

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35.400 Wrong Dose

Item Number: 190558
Eye Plaque: Under Dose 1

- 13 I-125 seeds
- Total activity of 1,793.17 MBq (48.464 mCi).
- The prescribed dose was 8,500 cGy (rem) with a planned treatment time of 101 hours.
- After the implant, the patient complained of excessive pain – the eye plaque became dislodged from its proper position.
- Eye plaque was removed that same day.

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35.400 Wrong Dose (cont.)

- Dose estimate to the normal sclera and cornea was 190 cGy (rem) at a depth of 1 mm for an 8.5-hour exposure.
- Dose at 2 mm for the same time period is 150 cGy (rem).

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Medical Events 2020

35.600 Medical events **13**

HDR

- Gynecological 10
  - Wrong site 5
  - Catheter 2
  - Broken tandem 1
  - Dislodged applicator 1
  - Wrong plan 1

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Medical Events 2020 (cont.)

35.600 Medical events **13**

HDR

- Hand Skin lesion 1
  Digitization error
- Neck lesion 1
- Breast lesion 1

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35.600 HDR Events

Item Number: 200208
Wrong Site- cylinder perforated the vaginal wall **1**

- Prescribed three fractions using a HDR and a 407 GBq (11 Ci) Ir-192 source.
- During the third fraction, the vaginal cylinder was inserted, and it penetrated through the body wall weakened by previous surgery (robotic hysterectomy).
- The penetration allowed the source to move about 4 cm past the treatment area.
- As a result, the treatment area only received 25% of the volume coverage instead of the planned 95% volume coverage.

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Wrong Site- cylinder perforated the vaginal wall (cont.)

- The cause was human error.
- Corrective Actions:
  - Included procedure changes.
  - Retraining for AUs and staff.

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35.600 HDR Events

Item Number: 200135

Catheter- displaced cylinder 2

- Prescribed 600 cGy (rad) to the surface of the vaginal cylinder.
- Patient undergoing first fraction of a vaginal cylinder treatment using an HDR and a 271.95 GBq (7.35 Ci) Ir-192 source.
- Staff had difficulty removing the cylinder post-treatment.
- It was determined cylinder had perforated the patient's vaginal wall tissue following pre-treatment imaging and prior to completion of the treatment.
- The cylinder moved 3.5 cm from its original position and protruded into the bowel space.

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Catheter-Displaced Cylinder (cont.)

- Estimated unintended dose of 600 cGy (rad) to the bowel.
- Patient required immediate surgery to suture the vaginal wall and expected to recover.
- Cause: human error
- Corrective Actions:
  - At the time of cylinder insertion, they will put a pen mark on the inside of the patient's leg to mark the external terminus of the cylinder. Then during the final pre-treatment check, they can positively confirm that the cylinder is in the correct position.
  - That will improve the previous final pre-treatment check, which simply verified that the cylinder had not come out.

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35.600 Wrong Site

Item Number: 200393
Wrong site – Applicator inserted rectal cavity 3

- Prescribed 3,000 cGy (rad) to the vaginal cuff in five equal fractionated treatments of 600 cGy (rad) each.
- Error was noticed after third fraction was delivered, since fecal matter was in the applicator.
- Dose delivered was 146 cGy (rad), which was 76% less than prescribed.
- Rectum was expected to receive 153 cGy (rad) but received 394 cGy (rad) to 50% of the rectum volume, which was 157% over intended.

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Applicator Inserted Rectal Cavity (cont.)

- The administration was not consistent with the treatment site specified in the written directive.
- Facility did have procedures for administrations requiring a written directive, but they lacked the specificity necessary to ensure the administration was in accordance with the written directive.

- Root Cause:
  - Failure to properly place the HDR applicator at the prescribed location
  - Failure of the treatment team to properly identify the error in subsequent radiographic images.

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Applicator Inserted Rectal Cavity (cont.)

- No adverse medical impact to the patient was reported and the next fraction was delivered without incident.
- Cause: human error
- Corrective Action:
  - Facility modified their written procedures to identify the appropriate cavity placement.

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35.600 HDR Events

Item Number: 200258

Wrong site- Applicator inserted rectal cavity 4

- Prescribed three fractions of 700 cGy (rad) delivered to the vagina using a HDR and 278.277 GBq (7.521 Ci) Ir-192 source.
- Presence of fecal matter was noted on the applicator after the first fraction.
- CT images were reviewed and determined that the applicator was placed in the patient's rectum instead of the vagina**.**
- 1% of the rectum received a dose of 1,250 cGy (rad) and approximately 50% of the rectal volume received a dose of 163 cGy (rad).

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Applicator Inserted Rectal Cavity (cont.)

- It was estimated that 90% of the target volume received 520 cGy (rad), or 74% of the prescribed dose.
- The dose acute effect to the rectum was expected to include temporary acute mucosal denudation, which should resolve in 21 days. That process may result in increased stool frequency and urgency.
- The cause of the event was determined to be inadequate supervision by the AU.

- Corrective Actions:
  - Included generating a new written procedure.

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35.600 HDR Events

Item Number: 200233
Wrong site- Wrong area treated 5

- Prescribed three fractions of 700 cGy (rad) to vaginal cuff, for a total dose of 2,100 cGy (rad).
- During second fraction the event happened, when the wrong area was treated with an estimated dose of 250 cGy.
- After treatment, evidence of improper placement was noticed.
- Vaginal cuff received 80.9% of the intended dose.

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Wrong site- Wrong area treated (cont.)

- Treatment plans were reexamined for proper treatment during the third and final fraction.
- Third treatment included 800 cGy (rad) to the vaginal cuff and no issues were noted.
- The cause was human error.
- Corrective actions included procedure changes.

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35.600 HDR Events

Item Number: 200378
Catheter- wrong catheter 1

- Prescribed two treatments to the vaginal cuff of 600 cGy (rad) each using a HDR with a Ir-192 source [255.781 GBq (6.913 Ci)].
- During second treatment, it was noted that the source catheter tube used in the first boost treatment was too long; it measured 120 cm instead of the intended 113 cm.
- Treatment was delivered to the surface of the lower vagina instead of the vaginal cuff. The lower vagina received 600 cGy (rad).

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Catheter- wrong catheter (cont.)

- Revised plan to perform an extra treatment to the area that was underexposed in the first treatment.
- The cause of the event was human error.
- Corrective Actions:
  - Included labeling the catheters with lengths, modifying procedures, and providing additional instruction to personnel.

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35.600 HDR Events

Item Number: 200275
Catheter- Wrong data catheter entry 2

- Prescribed intended organ dose was 2,400 cGy (rad).
- Due to an incorrect entry of the catheter length into the treatment delivery system, an unintended dose of 2,180 cGy (rad) was estimated to have been delivered to the large bowel.
- The dose delivered to the intended organ was initially estimated to be 0 cGy (rad).
- The cause of the event was human error.

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Catheter- Wrong data catheter entry (cont.)

- Error was due to the failure of the technician to correctly change the distance in the treatment plan.
- Corrective Actions:
  - Included labeling the catheters with lengths, modifying procedures, and providing additional training to personnel.

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35.600 HDR Events

Item Number: 200257

Broken tandem 1

- Prescribed a total of 2,750 cGy (rad) in five fractions of 550 cGy (rad) each.
- The patient was treated with an HDR unit using a tandem and ring along with a 192.07 GBq (5.191 Ci) Ir-192 source.
- During the completion of the third fraction, the device was removed from the patient and discovered that the tandem had broken into two pieces.
- No warnings or errors from the machine were recorded from either the check source or the treatment cable.

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Broken Tandem (cont.)

- The break in the tandem occurred about four inches from the end of the tandem, at the beginning of the bend on the insertion end at the start of the ring.
- The licensee could not confirm where the source was, if it did not travel along the tandem after the break, the dose to other possible tissue would have ranged from 450 to 600 cGy (rad).
- The tandem was used a total of 53 times prior to this event.
- Corrective Actions:
  - Facility modified their procedure to require all views of the markers to be reviewed prior to treatment. They will periodically x-ray the tandems to make sure there are no flaws.
  - The manufacturer investigated the incident as well. A clearly identified root cause was not identified by the manufacturer's investigation.

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35.600 HDR Events

Item Number: 200001

Dislodged Applicator 1

- Prescribed dose was 600 cGy (rad) using a 189.66 GBq (5.126 Ci) Ir-192 source.
- Treatment was being conducted using a remote after loader unit with a tandem and ovoid applicator.
- The applicator was found dislodged at the end of the treatment period.
- The patient was receiving fraction four of five planned fractions when the incident occurred.
- It was unknown how long the applicator was not in the planned position or what caused it to move.

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Dislodged Applicator (cont.)

- Observed skin effects were described as "moist desquamation" due to the applicator being dislodged from the vaginal canal and positioned against the skin.
- The evidence suggests that the applicator was against the skin long enough to deliver a skin dose in the range of 1,000 to 3,000 cGy (rad).
- Cause: human error
- Corrective Actions:
  - Update procedures and providing retraining.

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35.600 HDR Events

Item Number: 200206
Wrong plan-digitization error 1

- A balloon applicator, an HDR and a 444 GBq (12 Ci) Ir-192 source were used for treatment.
- A treatment plan was generated to deliver 3,400 cGy (rad) in 10 fractions, with twice-a-day fractionation with a minimal 6-hour interval between fractions, for five days.
- The treatment was completed uneventfully.

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Wrong plan-digitization error (cont.)

- During routine retrospective review of the case, an error was discovered in the treatment planning process.
  - All catheters were planned with a digitization error, which incorrectly shifted the dwell positions forward by approximately 8 mm.
- The error was not discovered until after the patient completed treatment.
- When the digitization error was corrected, the planned treatment volume coverage delivered was only 68%. The patient only received 2,310 cGy (rad).

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Wrong plan-digitization error (cont.)

- Licensee concluded that the dose to critical structures, such as skin and ribs, did not exceed established parameters.
- There were no acute ill effects on the patient.
- Cause: human error
- Corrective Actions:
  - Facility performed a change in policy to have a second physician/dosimetrist review all high dose rate plans performed prior to initiation of treatment.

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35.600 HDR Events

Item Number: 200083

Hand skin lesion- digitization error 1

- Patient received 56.25% less dose than prescribed and dose to an unintended site during skin therapy.
- The patient was scheduled to receive five fractions, at 750 cGy (rad) per fraction, on five different skin lesions of the left hand.
- The applicator was attached to the patient specific immobilization device. The physician marked the lesions which were to be treated with 1 at the thumb and 15 at the pinky finger.
- Neither the physicist or the person providing information on the treatment were present during the simulation.

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Hand Skin Lesion-Digitization Error (cont.)

- The physicist set up the treatment plan starting in reverse order.
- In addition, non-target skin (normal skin) unintended to be irradiated received 750 cGy (rad).
- Corrective Actions:
  - Were taken during simulation, during the independent physics check, and during the time out prior to delivering the first treatment.
  - Informative set-up pictures will be taken, clearly labeling orientation of any devices.
  - Catheters will be numbered in a clockwise fashion for consistency.

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35.600 HDR Events

Item Number: 190571

Neck lesion 1

A dose of 1,800 cGy (rad) was prescribed to the neck in three fraction of 600 cGy (rad).

- Treatment with HDR and a 233.026 GBq (6.298 Ci) Ir-192 source.
- During the first fraction the patient received a dose to the prescribed treatment site of approximately 30 cGy (rad), the dose was delivered at 91.5 cm instead of the intended 118.1 cm, because the guide tube and catheter were not connected properly.

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Neck Lesion (cont.)

- After the measurement error was corrected, the first fraction was delivered correctly. The second and third fractions were delivered to the target tissue without problems.

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Neck Lesion (cont.)

- Cause was determined to be human error.
- Corrective Actions:
  - Included verification by a second AMP for correct connection of the guide tube and catheter.
  - Checking the software for catheter length, and staff will be present for the next case utilizing catheters.

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35.600 HDR Events

Item Number: 200214

Breast lesion- Device Malfunction 1

- HDR and a Ir-192 source with an activity of 318.2 GBq (8.6 Ci).
- Patient to receive 10 channels of treatment.
- Error was noted when treatment from the third channel was attempted. The source was retracted back into the safe position. Staff reset the HDR unit and rebooted.
- The unit functioned normally for the fourth channel. However, during the fifth channel the machine experienced another fault, but the source did not automatically retract.
- Staff then attempted two emergency stop procedures, but both failed.

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Breast lesion- Device Malfunction (cont.)

- Staff manually retracted the source after approximately two to four minutes.
- Patient was disconnected from the catheter, everyone was immediately removed, and the room was secured from entry.
- The patient and staff were surveyed after the incident and all readings were at background. The manufacturer was contacted.
- Service technicians removed the source from the afterloader. It appeared that the source became stuck approximately 4 to 5 inches from the shielding park position (inside the afterloader, but outside the shielded safe).

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Breast lesion- Device Malfunction (cont.)

- The preliminary dosimetry report indicated that three staff members received minor radiation exposures.
- Cause: Device Malfunction
- Corrective Actions:
  - Manufacturer updated hardware and software
  - For aborted treatment - entire review process to be re-done to confirm no changes to the patient setup or treatment plan parameters.
  - Pretreatment report to be printed out, reviewed, and compared to the approved treatment plan.
  - Both treatment console and TV to be monitored at all times during treatment.
  - Training in updated time out and plan verification process.

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Medical Events 2020

35.1000 Medical events **27**

- **Perfexion** **2**
- **Intravascular Brachytherapy** **1**
- **Radioactive Breast Seed Localization** **1**

Y-90 Microspheres **23**

- Therasphere® 15
- SirSphere® 8

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35.1000 Perfexion

Item Number: 200136

Perfexion - Head frame slipped **1**

- After completing treatment:
  - It was discovered that anterior screws location securing the patient's head in the treatment position had moved.
- Service engineers were called in to attempt to identify any problems.
- Estimated delivery to the left vestibular schwannoma target coverage area (volume of tissue receiving dose) was 44%.
- Estimated dose to the target was 400 cGy (rad).

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Perfexion - Head frame slipped (cont.)

- Unintended dose to a region of the left temporal lobe was estimated to be 1,360 cGy (rad).
- The patient was informed of the incident.
- Corrective Actions:
  - Included having the radiation therapist ensure patient understands that any movement of their head within the headframe is not anticipated and should be communicated immediately.
  - New protocols were also adopted aimed at further reducing the possibility of such occurrences.

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35.1000 Perfexion

Item Number: 190538

Perfexion-Equipment Failure 2

- Patient received less dose than prescribed due to an equipment failure.
- The treatment was interrupted when the High-Definition Motor Management tracking system lost communication with the equipment.
- Sources safely retracted into their home position.
- Software prompted the user to reinitiate the system.
- An error message occurred on each attempt to reinitiate the system. The system was then rebooted, but the same error occurred again.

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Perfexion-Equipment Failure (cont.)

- Patient was removed from the treatment vault and a service call was made.
- It was estimated that the patient received between 93 and 96% of the intended 1,800 cGy (rad) to the left frontal target (50% isodose line). However, the patient received none of the prescribed dose of 1,800 cGy (rad) to the right posterior target (90% isodose line).
- No overdose occurred and no harm to the patient was expected.

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35.1000 Intravascular Brachytherapy

Item Number: 200189

Wrong site 1

Patient received dose to two unintended locations.

- The treatment site was intended to receive a treatment time of 5 minutes and 57 seconds, for a prescribed dose of 2,300 cGy (rad), - it received 0 cGy (rad).
- The source train did not advance to the designated treatment site during two attempts.
- The source train got stuck in the beta-rail catheter proximal to the treatment area for 6 minutes and 54 seconds.
- That area, the descending aorta, received 0.3 mGy (30 mRad).

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Wrong site (cont.)

- During a second attempt, the source train got stuck again in the descending aorta, for 3 minutes and 41 seconds.
  - That area received 0.2 mGy (20 mRad).
  - The intended treatment site received 0 cGy (rad).
- The source train was able to fully retract into the IVB device each time.
- The source got stuck inside the patient both times, radiation exposure to staff was negligible.
- Vendor determined the 6F guide extension catheter used was too small – needed 7 F or larger.

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Wrong site (cont.)

- The source train became stuck inside the catheter due to compression and deformation of the catheter lumen.
- Vendor recommended that a failed hydraulic delivery or return be followed by manual catheter removal after 15 seconds.
- Corrective Actions:
  - Included hands-on refresher training with the vendor for all cardiologists, AU, and AMP.
  - Revised their timeout protocol/checklist to address emergency procedures and adherence to the vendor's 15 second removal recommendation and guide catheter/guide extension requirements

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35.1000 Radioactive Breast Seed Localization

Item Number: 190572
Breast: Seed Migration 1

- Patient was implanted with two I-125 localization seeds
- Surgeon noticed that one of the seeds had migrated about two inches from its original implant location in the left breast.
- The seed contained an activity of 7.4 MBq (200 μCi).
- The surgeon and radiologist concluded that any attempt to retrieve the seed in question would compromise patient care.
- As a result, the seed was not retrieved.

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Breast: Seed Migration (cont.)

- Doses to the patient for the lifetime of the seed were: calculated to be:
  - 493 cGy (rad) at 1 cm,
  - 123 cGy (rad) at 2 cm, and
  - 31 cGy (rad) at 3 cm.

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35.1000 Medical Events

Y-90 Microspheres **23**

Therasphere ® **15**

- Procedure not followed 1
- Device connection leak 1
- Catheter issues 4
- Wrong lobe 1
- Tubing occlusion 3
- Spill 1
- Clumping 2
- Equipment failure 1
- Unknown failure 1

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35.1000 Y-90 Therasphere® Events

Item Number: 200304

Procedure not followed **1**

Patient was prescribed 20,000 cGy (rad), but only received11,590 cGy (rad).

- A patient received 58% of the prescribed dose during a Y-90 microsphere therapy.
- The underdose was based on pre- and post-administration measurements of the dose vial and waste container.

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35.1000 Y-90 Therasphere® Events (cont.)

- The microsphere delivery system was sent back to the manufacturer to determine if an equipment failure occurred.
- The manufacturer noted deviations from the recommended delivery protocol.
- There was no expected harmful patient impact.
- Corrective Actions:
  - Procedural review and revision and personnel retraining.

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35.1000 Y-90 Therasphere® Events

Item Number: 200279
Device connection leak 1

The prescribed dose was 15,000 cGy (rad) and the delivered dose of 11,320 cGy (rad).

- Received 24.53% less dose than prescribed.
- A leak was noted, and treatment was stopped to facilitate cleanup.
- Contamination was contained and removed to be incinerated.
- Cause:
  - Bad connection of the outlet tube from the microsphere administration device.

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35.1000 Y-90 Therasphere® Events (cont.)

- Corrective Actions:
  - Included procedure modifications to require that the interventional radiologist flush the infusion catheter to ensure flow prior to connection with the outlet tubing.
  - No catheter extension or extra fittings are to be used; if the catheter is too short, replacement is required. Additionally, one physician will firmly connect the outlet tube to the infusion catheter and the second physician will visually verify the connection.
  - During initial delivery, both physicians will observe the outlet line and infusion catheter for proper operation.

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35.1000 Y-90 Therasphere® Events

Item Number: 190612
Spill **1**

Prescribed a dose of 18,400 cGy (rad) but was only administered about 39.5% or 7,270 cGy (rad).

- Both delivery and nuclear medicine pre-procedure preparation were performed following facility procedures.
- Remaining undelivered dose became stuck/trapped in the transport vial and could not be administered.
- A small amount of microspheres spilled onto the administration table, which was covered with absorbent towels.

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35.1000 Y-90 Therasphere® Events (cont.)

- Staff isolated the contamination, scanned all areas to ensure contamination was not spread outside the immediate area, and called for assistance with clean-up.
- Contamination was cleaned-up:
  - all swipes were counted, and results showed no residual contamination in the suite or on any equipment in the suite.
  - Manufacturer was notified
- Corrective Actions:
  - Physician and RSO will monitor the pressure relief vial for increased back pressure.
  - Have verbal countdown for administration pressure during the administration.
  - Terminate procedure when excessive back pressure cannot be corrected by simple catheter manipulation.

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35.1000 Y-90 Therasphere® Events

Item Number: 200363
Catheter issues- catheter slipped 1

Prescribed 30,000 cGy (rad) and received 21,500 cGy (rad)

- Clinic tried to perform a split dose procedure on the patient's anterior right liver lobe and posterior right liver lobe.
- Each site was prescribed a dose of 15,000 cGy (rad).
- The posterior site was treated first and then the catheter was moved to the anterior position.

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35.1000 Y-90 Therasphere® Events (cont.)

- Post treatment scans:
  - Indicated that the posterior site received 3,500 cGy (rad), while the anterior site received 18,000 cGy (rad).
- Catheter slipped after initial placement, resulting in the medical event.
- Corrective Action:
  - Clinic no longer conducts split dose procedures.
  - Now a formal time-out in the procedure room when a dosage is brought into treatment room - includes the same checklist as the original procedural time-out, in addition to the prescribed and assayed dosage.

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35.1000 Y-90 Therasphere® Events

Item Number: 200005
Catheter-wrong tubing 2

Patient prescribed a dose of 11,300 cGy (rad) posterior and 11,800 cGy (rad) anterior. Patient received a dose of 11,300 cGy (rad) posterior and 2,978 cGy (rad) anterior.

- Prescribed a split dose of microspheres.
- Patient was tall and a longer catheter tube than the standard size of 160 cm was used, along with an extension tube and attachment.
- AU noticed that the container for the anterior administration was hot.

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35.1000 Y-90 Therasphere® Events (cont.)

- Measurements indicated that 25% of the activity was delivered to the anterior section.
- The patient returned for another treatment without problems.
- Cause: human error
- AU did not realize that microspheres accumulate at the attachment points and in the extension tubing.
- Corrective Actions:
  - Included educating all interventional radiologists that no additional connections should be made between the microsphere administration system and the delivery microcatheter except those authorized by the manufacturer.

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35.1000 Y-90 Therasphere® Events

Item Number: 190505
Catheter-extension tube issue 3

Prescribed a dose of 15,900 cGy (rad) and received 800 cGy (rad).

- AU chose a trans-radial approach for hepatic delivery of microspheres instead of transfemoral.
- Administering physician had difficulty setting up the injection apparatus and used an extension tube to reach from the patient catheter to the microsphere delivery system.

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35.1000 Y-90 Therasphere® Events (cont.)

- Manufacturer informed the facility the use of extension tubes is prohibited.
- The package insert states, “do not use a catheter extension or extra fittings - replace the catheter if it is too short.”
- The bulk of the microspheres remained in the tubing
  - no contamination was found in the area where the treatment occurred.
- The RSO stated there would be no adverse effect to the patient.

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35.1000 Y-90 Therasphere® Events (cont.)

- Corrective Actions:
  - Included retraining of all AU users and technologists assigned to interventional radiology by the microsphere supplier, with emphasis to never supply the radiologist with any extension tubing for microsphere treatments.

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35.1000 Y-90 Therasphere® Events

Item Number: 200212
Catheter-kink microcatheter 4

Patient was prescribed 12,000 cGy (rad) to the left hepatic lobe using 1.62 GBq (43.78 mCi) of Y-90 microspheres.

- Microcatheter was positioned in left hepatic artery and verified with arteriogram.
- After administration only a portion of the dose was delivered as the catheter quickly became occluded.
- Due to patient's tortuous hepatic vasculature, the assessment was that a kink in the microcatheter prevented the majority of the dose from being delivered.

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35.1000 Y-90 Therasphere® Events (cont.)

- Pre- and Post- administration equipment measurements revealed that only 17% of the prescribed dose was delivered.
- Post treatment surveys of all gowns, syringes, gloves, drapes, floor coverings, and the trash revealed no contamination of the surgical suite.
- Post treatment planar imaging revealed no extrahepatic deposition of activity.

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35.1000 Y-90 Therasphere® Events (cont.)

- Patient returned for a second attempt at treating the left hepatic lobe.
- The patient was treated to 12,000 cGy (rad).
- The dose was delivered, as expected, to within 0.5% of the prescribed dose.
- Two changes were made in the procedure from the first attempt.
  - Rather than using left radial access, the right femoral artery was used for access.
  - A larger microcatheter was used.

81

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35.1000 Y-90 Therasphere® Events

Item Number: 200320
Wrong lobe 1

- Patient was prescribed 22,500 cGy (rad) to the right liver lobe.
- Patient was administered 2.66 GBq (62.9 mCi) of Y-90 microspheres.
- Post implant Bremsstrahlung imaging indicated that 2.01 GBq (54.39 mCi) was unintentionally delivered to Segment 4 of the left liver lobe, for a dose of 16,000 cGy (rad).

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35.1000 Y-90 Therasphere® Events (cont.)

- Event likely caused:
  - By incorrect placement of the tip of the intra-arterial catheter into a branch of the left hepatic artery.
- Contributing factor:
  - Patient's distorted anatomy, due to atrophy of the right lobe of the liver and hypertrophy of the left lobe.
- Patient was asymptomatic and liver tests for five days after the treatment were stable but radiation damage to the liver may not become apparent for up to two weeks post treatment.
- To prevent recurrence, additional imaging will be acquired when clinically indicated.

83

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35.1000 Y-90 Therasphere® Events

Item Number: 200169
Tubing occlusion 1

Only 62.7% or 7,530 cGy (rad) of the planned dose was administered to Segment 6 of the liver.

- Prescribed a total of 2.47 GBq (66.76 mCi) of microspheres, with 2.25 GBq (60.81 mCi) prescribed to the liver because of 9.1% lung shunting.
- Only 1.536 GBq (41.51 mCi) was administered and 1.4 GBq (37.84 mCi) went to the liver.
- Significant flow resistance was noticed during administration.
- No kinks along the catheter course external to the patient or internally under fluoroscopy were visualized.

84

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35.1000 Y-90 Therasphere® Events (cont.)

- AU believed that there was blockage on the labeled tubing of the administration set.
- Procedure was stopped.
- Patient had a subsequent segmentectomy without incident using tubing from a box set from a different lot number.
- No adverse effects to the patient were anticipated and the patient and referring physician were notified the day of the event.
- Corrective Action:
  - Sent administration set was sent back to manufacturer after it decayed to background for further investigate a possible cause

85

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35.1000 Y-90 Therasphere® Events

Item Number: 200071
Tubing occlusion 2

Prescribed 13,500 cGy (rad) to the right lobe and 13,500 cGy (rad) to left lobe.

- Received less dose than prescribed during treatment.
- Both doses were administered, and no unusual signs were observed by the AU.
- After each dose, microcatheters and delivery system tubing were measured to calculate residual activity.
  - Patient received 4,550 cGy (rad) to the right lobe and 12,940 cGy (rad) to the left lobe.

86

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35.1000 Y-90 Therasphere® Events (cont.)

- Possible occlusion in either the microcatheters or delivery set tubing.
- Malfunctioning dosimeter was identified.
- Corrective Actions:
  - Have verbal countdown for administration pressure during the administration.
  - Terminate procedure when excessive back pressure cannot be corrected by simple catheter manipulation.
  - The RADOS dosimeters will be checked prior to each administration. A secondary instrument will also be used to confirm dosimeter readings.

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35.1000 Y-90 Therasphere® Events

Item Number: 200336
Tubing occlusion 3

Prescribed 14 GBq (378.38 mCi) of Y-90 microspheres.

- As infusion initiated, it became apparent the patient was not receiving the dose.
- Physician was unable to clear the blockage in the tubing.
- High resistance was felt during infusion.
- Procedure was terminated.
- Approximately:
  - 93% of activity remained in the device.
  - 5% of activity ended up in the waste material.
  - 2% was administered to the patient

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35.1000 Y-90 Therasphere® Events (cont.)

- Corrective Actions:
  - Terminate procedure when excessive back pressure cannot be corrected by simple catheter manipulation.
  - Providing retraining to personnel.

89

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35.1000 Y-90 Therasphere® Events

Item Number: 200286
Clumping in microcatheter 1

- Prescribed 51,160 cGy (rad), but only received 35,890 cGy (rad).
- No issues with the administration; one microsphere bolus was administered followed with three additional flushes of saline.
- Residual activity reading in the waste container was higher than usual.
- The administration was performed by an experienced AU, while following the manufacturer's instructions for use.

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35.1000 Y-90 Therasphere® Events (cont)

- Event occurred due to unseen clump of microspheres that aggregated in the microcatheter.
- Clumping did not clear with the performed flushing.
- Sufficient activity was delivered to the target volume to achieve a clinically effective dose.
- There was no adverse effect expected from the treatment.
- No action was taken to prevent recurrence, since the administration was performed in compliance with the manufacturer's instructions.

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35.1000 Y-90 Therasphere® Events

Item Number: 200314
Clumping **2**

Patient was prescribed a dose of 200 cGy (rad) and received 62 cGy (rad).

- During administration, the AU observed that pressure became significantly less than expected and the activity leaving the dose vial into the catheter decreased significantly before the entire dose could be delivered.
- Flow from the administration vial could not be re-initiated.
- AU chose to end the procedure.

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35.1000 Y-90 Therasphere® Events (cont.)

- Following surveys of the dose administration vial, it was determined the patient received a dose of 62 cGy (rad).
- Contamination surveys were conducted and no levels above any limits were detected.
- Cause: Unnoticed microspheres that aggregated within the catheter and device malfunction that occurred as an effect of the aggregation.
- The equipment was returned to the manufacturer for evaluation. They tested the device and it functioned as expected.

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35.1000 Y-90 Therasphere® Events

Item Number: 200193
Equipment Failure 1

Patient received 11.5% of the prescribed dose to the left liver lobe. The intended activity was 3.6 GBq (97.3 mCi) of Y-90.

- Delivery device malfunctioned as the technician experienced increased pressure in the line when administering.
- The therapy was aborted after a few failed attempts.
- The patient was aware and planned to return for the remainder of the dose.
- Facility contacted the vendor, who will discard the malfunctioned device.

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35.1000 Y-90 Therasphere® Events

Item Number: 200075
Unknown failure 1

Prescribed a dose of 12,000 cGy (rad) and received a dose of 8,520 cGy (rad).

- Remaining microspheres in tubing could not be flushed.
- Procedure was stopped.
- Radiologist determined that the ME was of no clinical significance in terms of complications.
- Additionally, there would be no change to the patient in terms of tumor management or therapy treatment.

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35.1000 Y-90 Therasphere® Events (cont.)

- Manufacturer came to the facility, and observed three microsphere procedures, with no reported issues.
- The cause of the failure could not be determined after review was completed.

- Corrective Action:
  - Facility provided additional training to the individuals involved in the event.

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35.1000 Medical Events

SirSphere ® 8

- Vial leakage 2
- Equipment – ruptured line 1
- Catheter 5

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35.1000 Y-90 SirSphere® Events

Item Number: 200366
Vial leakage **1**

The patient was prescribed 83.7 mCi and 58.2 mCi were delivered. Only 70% of dose was delivered.

- At the end of the administration, the delivery vial appeared to overfill as the radiologist attempted to mix the microspheres with a contrast agent.
- Radiologist noticed clumping and, after attempting to gently disperse the microspheres, he gave a couple hard pushes of the mix into the delivery vial. At that time, he noticed a leak.

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35.1000 Y-90 SirSphere® Events (cont.)

- Further examination showed that the material leaked out of the sides of the crimped vial top rather than the septum. The procedure was stopped to prevent further contamination.
- Corrective Actions:
  - Facility provided additional training to the AU and staff members involved in the event.
  - Increase height of the dose vial above the patient catheter input port to provide added gravity assist.
  - Inserting needles into the vial septum at an angle to keep needles from moving and cause stretching of the rubber cap from weight of attached tubing.

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35.1000 Y-90 SirSphere® Events

Item Number: 200190

Vial leakage 2

- Patient was prescribed 800 MBq (21.62 mCi) and received 400 MBq (10.81 mCi) of Y-90 microspheres.
- Prescription to be provided in two doses:
  - each containing 400 MBq (10.81 mCi).
- First dose was successfully administered.
- Second dose was not delivered since a problem developed.
  - While pushing saline into the V-Vial, pressure built and vented out the top of the vial rather than pushing the microspheres through the tubing into the patient.
- Vented either from the side of the septum or around the needle.

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35.1000 Y-90 SirSphere® Events (cont.)

- Administration box contained the leakage and prevented wider contamination.
- Administration was stopped.
- Most of the intended dose remained in the Plexiglas box that was used for shielding.
- Cause: Operator error
- It was noted the septum contained six punctures, instead of the normal four punctures. Also, the needle piercings were not made straight and perpendicular to the septum surface.
- The puncture paths possibly intersected with other puncture paths located closely together.

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35.1000 Y-90 SirSphere® Events (cont.)

- These factors reduced the ability of the septum to seal firmly around the needle shafts.
- Vendor recommends a minimum spacing between needle punctures of 2 mm or 1/8 inch.
- Leakage possibility is also increased by any side-wards pressure or tension that may have been applied to the needles or tubing during administration.
- Corrective Actions:
  - Involved medical personnel reviewed the proper piercing technique of the vial septum.
  - Facility began using a different delivery system and all personnel have been trained on it.

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35.1000 Y-90 SirSphere® Events

Item Number: 190597
Equipment – ruptured line 1

- Prescribed 555 MBq (15 mCi) of Y-90 to the left liver lobe.
- Catheter became blocked during treatment.
- Radiologist increased the pressure in an attempt to clear the line and the A Line (last length of system tubing connected to the catheter) ruptured.
- Patient received less dose than prescribed during treatment.

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35.1000 Y-90 SirSphere® Events (cont.)

- Nominal dose to the tumor was 25,660 cGy (rad) and the delivered dose was 16,290 cGy (rad).
- Nominal dose to the liver was 2,640 cGy (rad) and the deliver dose was 1,680 cGy (rad).
- Nominal dose to the lung was 25 cGy (rad) and the delivered dose was 16 cGy (rad).
- No contamination of staff occurred, only of the patient and floor of the suite.
- Decontamination of the room and patient followed.
- No contamination on the patient's skin, only on his gown and on the tube.

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35.1000 Y-90 SirSphere® Events (cont.)

- Problems with imaging occurred and there were no images of the patient's treatment.
- A pre- and post-procedure measurement of the microsphere container concluded that about 63.5% of the prescribed dose was delivered, but most of the delivered microspheres were lost in the spill.
- Cause: The incident is believed to be caused by mechanical failure of tubing line used.
- Corrective Actions: Updating procedures and retraining personnel.

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35.1000 Y-90 SirSphere® Events

Item Number: 200373

Catheter – Clogged/tip 1

- Prescribed 1.67 GBq (45.1 mCi) and delivered 1.12 GBq (30.3 mCi) of Y-90 microspheres.
- Microspheres became clogged in the applicator.
- Cause: Issues with the delivery catheter during the procedure - catheter clogged, removed, and replaced during the procedure.
- Corrective Actions:
  - Microcatheter and angled tip was root cause of the clog.
  - Manufacturer indicated all types of catheters can clog in normal use.
  - AU will use a microcatheter without the angled tip to avoid a similar event.

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35.1000 Y-90 SirSphere® Events

Item Number: 200330

Catheter – Clogged 2

- Prescribed dose was 1.44 GBq (38.92 mCi) and the delivered dose was 0.67 GBq (18.11 mCi) of Y-90.
  - received 47% of the prescribed dose.
- Catheter could not be flushed - procedure stopped.
- Cause: First time using the microcatheter.
  - Uses a balloon to prevent potential backflow of the dose.
  - Smaller lumen than the catheters routinely used for this purpose.
- Corrective Action:
  - Catheter model will not be used for future treatments.

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35.1000 Y-90 SirSphere® Events

Item Number: 200155

Catheter – Activity remained in tubing, vial and catheter 3

- Prescribed 962 MBq (26 mCi), but only received 592 MBq (16 mCi) of Y-90.
- An assay revealed that 370 MBq (10 mCi) remained in the tubing, vial, and catheter.
- AU determined that this was not the result of vascular stasis. Equipment was evaluated in an attempt to determine the cause.
- Cause: a clog or other issue with either the stopcock or the microcatheter.
- Corrective Action: procedure updates

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35.1000 Y-90 SirSphere® Events

Item Number: 190602

Catheter – Residual activity in tubing 4

- Prescribed 144.3 MBq (3.9 mCi) but only received 105.3 MBq (2.85 mCi), (27% less than prescribed).
- AU stated that the patient had unusually small blood vessels feeding the tumor. The RSO stated that there were no errors or problems during the administration.
- Incident appeared to be a medical event solely because the intended dose was small and the residual material remaining in the tube of the administration kit was greater than 20%.
- There was no failure of the equipment, deviation from procedures, or human error.

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35.1000 Y-90 SirSphere® Events

Item Number: 190577

Catheter- occluded 5

- Prescribed a dose of 11,000 cGy (rad) and received 14 cGy (rad) to the liver.
- The patient treatment was aborted due to a kinked microcatheter.
- 99.5% of the prescribed microspheres was not delivered to the treatment site.
- A 0.7 mm catheter with a length of 130 cm was initially used to access the treatment site. Following an unsuccessful attempt, a 0.5 mm catheter with a length of 130 cm was then used.
- Both catheters were unsuccessful.

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35.1000 Y-90 SirSphere® Events (cont.)

- Contamination of the radiology suite floor was detected.
- Contamination of infusion paraphernalia (gloves, shoe covers, gauze, and towels) was also detected.
- A nalgene container with the undelivered dose vial and a second nalgene container with the delivery catheter were measured.
- Of the total drawn activity of 1.64 GBq (44.3 mCi), the Nalgene containers contained 1.63 GBq (44.1 mCi), while 7.4 MBq (0.2 mCi) was administered.
- Liver received a dose of 14 cGy (rad). Dose to the unintended organ (pancreas) was also calculated to be 14 cGy (rad).

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35.1000 Y-90 SirSphere® Events (cont.)

- The incident was a result of occlusion within the catheter used to deliver the microspheres.
- Corrective Actions:
  - Future administrations will follow the manufacturer's recommended instructions for catheters used in microsphere administration.
  - Procedure updates

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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

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Acronyms

- I-125 – Iodine-125
- I-192 –Iridium-192
- IV – Intravenous
- IVB – Intravascular Brachytherapy
- Lu-177 – Lutetium-177
- MBq – Mega Becquerel
- mCi – millicurie
- RSO – Radiation Safety Officer
- Y-90 – Yttrium-90

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QUESTIONS?

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