



Status of Medical Events FY 2018

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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 2013 - 2015

- 43 Medical events reported - FY 2013
- 46 Medical events reported - FY 2014
- 57 Medical events reported - FY 2015

	<u>FY13</u>	<u>FY14</u>	<u>FY15</u>
35.200	0	1	3
35.300	2	3	8
35.400	15	5	9 (10*)
35.600	10	10	17
35.1000	16	27	20 (30)

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

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Medical Events FY 2016 - 2018

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

	<u>FY16</u>	<u>FY17</u>	<u>FY18</u>
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)

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Medical Events 2018

35.300 Medical events **2**

Iodine-131 MIBG 1
Radium-223 1

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35.300 Medical Events

Iodine-131 MIBG **1**

- **50,000 to 12,000 cGy skin dose to 15 cm²**
 - Patient was disconnected from infusion pump at Spiros connection to use restroom.
 - At end of procedure, high activity of I-131 on patient's clothing and bed linen.
 - Two days later, patient reported discomfort and reddening of skin on upper right thigh erythematous lesion to desquamation the next day.

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35.300 Medical Events

Iodine-131 MIBG (cont.)

- **50,000 to 120,000 cGy skin dose to 15 cm²**
 - Did not decontaminate patient until signs of erythema.
 - Will only disconnect patient if medical emergency.
 - Will use adsorbent pads under administration line.
 - Will develop patient specific decontamination procedures.

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35.300 Medical Events

Ra-223 dichloride **1**

- **Administered 176.1 µCi instead of 180 µCi**
 - Signed written directive called for oral administration
 - Technologist administered intravenous
 - Will implement new written directive
 - Review current policy and procedures with staff

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Medical Events 2018

35.400 Medical events **13 (15)**

Eye Plaque	1
Unknown procedure	1
Prostate	9 (11)
One licensee, 3 reports	3 (5)
Human error	2
Wrong site	1
Larger than pre-plan or swelling	2

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35.400 Medical Events

Eye Plaque **1**

- **Prescribed 8,600 cGy – received 6,500 cGy**
 - Used new model of eye plaque that differed from old model
 - Isodose curves differed from brachytherapy plan.
 - Dose was deeper than expected

10

35.400 Medical Events

Unknown Procedure **1**

- **70% of the intended dose was delivered**

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35.400 Medical Events

Prostate **9 (11)**

- **One licensee, 3 separate reports, 5 patients**
 - Report 1 - First patient prescribed 14,000 cGy, but administered 8,990 cGy – 62% of prescribed dose
 - No root cause, but attributed to human error
 - Some seeds may have migrated post-implant
 - Performed historical review after inspection
 - Second Patient prescribed 14,500 cGy, but received 19,200 cGy - 132% of the prescribed dose
 - Third Patient prescribed 14,500 cGy, but received 18,900 cGy - 130% of the prescribed dose

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35.400 Medical Events

One licensee, 3 separate reports, 5 patients (cont.)

- Report 2 - Patient prescribed 14,500 cGy, but received 10,500 cGy – 72.4% of the prescribed dose
- Report 3 - Patient prescribed 14,500 cGy, but received 7,000 cGy - 48% of the prescribed dose

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35.400 Medical Events

- **Patient prescribed 11,000 cGy, but received 5,815 cGy – 53% of dose**
 - Partial seed strand implanted in the bladder
 - Removed errant seeds immediately with cystoscopy
 - Attributed to human error
 - Corrective actions include:
 - New written procedure
 - Use of more needles, more seeds, and less aggressive sparing of the urethra
 - Stop using pre-loaded stranded seeds, so improperly implanted seeds can be individually

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35.400 Medical Events

- **Patient intended 10,800 cGy, but 50% of prostate received no dose**
 - Ultrasound volume of prostate was smaller on ultrasound pre-implant scan than CT post-implant scan
 - Real-time implantation with ultrasound did not permit potential visualization errors
 - Attributed to human error
 - Corrective actions include:
 - Additional training to personnel and improved supervision
 - Terminate the seed implant program due to low patient volume

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35.400 Medical Events

- **Patient prescribed 11,000 cGy, but received 6,215 cGy – 56.5% of dose**
 - Attributed to human error
 - Improve imaging techniques
- **Patient prescribed 14,400 cGy, but received only 73% of dose**
 - Attributed to 18% increase in prostate size compared to pre-plan
 - Planned intentional cooler coverage near rectum
 - Additional training to personnel

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35.400 Medical Events

- Patient intended 12,500 cGy, but received 1,000 cGy 12.5% of dose (Pd-103 seeds)
 - Used Foley catheter but inflated balloon in prostate urethra instead of bladder
 - 32 of 54 seeds placed outside prostate and 3 seeds could not be seen
 - Expect risk of radiation damage to rectum and surrounding tissue
 - Failed to locate Foley catheter compounded by using magnification factor of ultrasound device that did not give full view of relevant anatomy

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35.400 Medical Events

- Patient intended 12,500 cGy, but received 1,000 cGy 12.5% of dose (Pd-103 seeds) [cont.]
 - Physician and medical physicist will audibly concur on image quality before proceeding
 - Manufacturer reset new default magnification value that will initial view of relevant prostate anatomy
 - Once first seed is implanted, fluoroscopic image will be used to verify relative location of seed and Foley catheter is where it is expected to be

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35.400 Medical Events

- Patient prescribed 12,500 cGy, but received 9,670 cGy – 77% of dose (Pd-103 seeds)
 - Three seeds from one needle did not remain in place
 - Contributing factors:
 - AU's preference for peripheral loading
 - Potential rotation of the prostate during needle insertion
 - Pressure effects from using hydrogel to separate prostate from rectum
 - Corrective actions:
 - No longer implant needle between urethra and rectum - will use two needles offset on axis
 - Use stabilized needles during surgery

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Medical Events 2018

35.600 Medical events	10
HDR	
• Skin	1
• Breast	2
• Gynecological	7
Device malfunction	2
Wrong site	3
Human mistake	2

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35.600 HDR Events

Skin

1

- **Patient prescribed 8 fractions of 500 cGy each to temple area, but received 350 cGy on first 2 fractions**
- First physicist used incorrect setup – forgot to use accuform - second physicist used correct setup
- Wrong position - gap between treatment device and patient's skin

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35.600 HDR Events

Skin (cont.)

- Lack of policy for custom immobilization devices for skin treatment
- Therapist present at first treatment and any time there is a new physicist
- Photograph set up with and without patient to show accuform
- Barcode scanning to track custom set up devices

22*

35.600 HDR Events

Breast

2

- **Wrong site - 1,200 cGy to lateral breast skin**
- Patient contacted oncologist because of skin reaction
- Physicist used tip end instead of connector end in treatment plan
- Corrective actions:
 - Additional training to personnel

23

35.600 HDR Events

Breast

2

- **Wrong site - 1 cc volume of skin received 850 cGy instead of intended 256 cGy**
- Savi applicator – struts 2 and 6 mislabeled - changed orientation of the applicator – direction of radiation
- Corrective actions:
 - Second physicist to independently verify catheter struts in treatment plan.
 - HDR review checklist – verify digitization of struts in treatment plan
 - Add HDR plan review to monthly audit
 - Additional training to personnel

24

35.600 HDR Events

Gynecological

7

- **Device malfunction**
 - Patient to receive 1,500 cGy during 3 fractions in 13 dwell points
 - HDR unit malfunctioned at dwell point 9
 - Treatment adjusted after repair of the HDR unit

25

35.600 HDR Events

- **Device malfunction**

- Device failed to fully retract at completion of treatment fraction
- Dose of 100 cGy to patient thigh – source was 5 cm from cylinder guide tube connector
- Source wire was bent near source
- Delay in removing source from vicinity of patient and reporting the event to RSO

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35.600 HDR Events

- **Catheter movement - connector locking nut too loose, which allowed catheter to slide out**
 - Event discovered by skin reaction progressed to moist desquamation
 - Dose to skin of 5,154 to 8,555 cGy
 - Corrective action:
 - Retrain medical staff and AU
 - AU will double check all connections and placement before and after each treatment
 - Purchased new cylinder with new design

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35.600 HDR Events

- **Prescribed 6 fractions of 350 cGy each – first fraction received 2,100 cGy**
 - Total treatment time incorrectly entered into treatment planning system
 - Human error and poor decision making – started first treatment after hours – second physicist not available
 - Corrective actions:
 - Second physicist has to independently verify treatment plan
 - Physicist to check that plan was exported correctly to the treatment console

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35.600 HDR Events

- **Wrong Site – 587 cGy dose to small intestine and bowel instead of 220 cGy**
 - Patient’s pelvis had extensive damage from uterine cancer
 - Two dwell positions shifted to deliver dose to non-targeted small intestine/bowel in first of 3 fractions
 - Treatment plan modified for next 2 fractions
 - Licensee thought not reportable - 10 CFR 35.3045(a)(1) and (3); NRC determined reportable - 10 CFR 35.3045(a)(1)(iii) and (a)(3)

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35.600 HDR Events

- **Wrong site - 5.5 cm outside the treatment site received 500 cGy in 0.5 cm volume**
 - Channel 12 digitized twice with no digitization of Channel 13 (Channel 13 digitization included in Channel 12 with no dwell positions for 13)
 - Treatment plan displayed expected dose distribution to critical organs and tumor and no dwell positions for Channel 13
 - Physician approved the plan

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35.600 HDR Events

- **Wrong site - 5.5 cm outside the treatment site received 500 cGy in 0.5 cm volume (cont.)**
 - Patient discomfort (full bladder)
 - Physicist rushed to complete the plan and export to treatment console - error overlooked
 - Corrective action:
 - Second check by physicist that did not prepare the plan
 - Each channel will be carefully reviewed
 - Patient not brought to treatment area until plan has been checked and exported to console

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35.600 HDR Events

- **Wrong site - 100 cGy outside treatment site Prescribed 1,890 cGy, but received 1,675 cGy**
 - In first of three fractions digitize the catheter as linear instead of as a single curved catheter
 - Physicist failed to recognize the incorrectly reconstructed catheter shape in planning software
 - Treatment length of 15.7 cm instead of 9 cm

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35.600 HDR Events (cont.)

- **Wrong site - 100 cGy outside treatment site (cont.)**
 - Discovered on second fraction
 - Treatment plan was not enlarged so physicist could not see the dwell points overlapping
 - Corrective actions:
 - Enlarge each treatment plan in which the physicist signs off
 - Use of a formalized check list

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Medical Events 2018

35.1000 Medical events	25
Perfexion	1
Intervascular Brachytherapy	1
Radioactive seed localization	1
Y-90 Microspheres	22
Unidentified	2
Therasphere®	13
SirSphere®	7

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35.1000 Medical Events

- | | |
|------------------|----------|
| Perfexion | 1 |
|------------------|----------|
- **Device malfunctioned**
 - Device recorded an error and backup power was low, so the sources were returned to the shielded position
 - One-third of prescribed dose delivered

35

35.1000 Medical Events

- | | |
|------------------------------------|----------|
| Intravascular Brachytherapy | 1 |
|------------------------------------|----------|
- First extra long delivery catheter – source could not get to treatment site and retracted safely to unit
 - Second extra long treatment catheter – source still could not get to treatment site but source could not be returned to IVB unit; all catheters removed
 - Hydraulic return mechanism failed to return source.
 - No dose to treatment site and 39 cGy to surrounding tissue
 - Deformation of delivery catheter confirmed root cause

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35.1000 Medical Events

Radioactive seed localization 1

- Expected dose 12 cGy to tissue, but patient received 99 cGy to tissue
- Seed implanted and scheduled for removal 6 days later
- Insurance company rescinded approval after seed was implanted and required 3 medical opinions
- Surgery performed approximately 64 days after implant

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35.1000 Medical Events

Y-90 Microspheres 25

Unknown 2

38

35.1000 Unknown Y-90 Events

Unknown 2

- Prescribed 13,400 cGy to a segment of the liver, but received 10,300 cGy – 77% of intended dose
- Patient received 60% of prescribed dose

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35.1000 Medical Events

Y-90 Microspheres 25

Therasphere® 13 (14)

- Overdose 1
- Catheter/Obstruction 8
- Bubbles 2
- Backflow to contrast 1
- Human mistake 1

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35.1000 Y-90 Therasphere® Events

Overdose

- **Prescribed 13,600 cGy, but received 29,400 cGy**
 - Picked up wrong dosage, measured and compared activity to shipping box information and not the written directive
 - Shipping box was for next week's patient
 - Post administration calculations identified the medical event
 - Will add a dose verification step in interventional radiology

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35.1000 Y-90 Therasphere® Events

Dose in Waste Jar

- **Prescribed 12,000 cGy administered 1,770 cGy – liver volume - 14% of intended dose**
 - Licensee thought equipment did not function as designed
 - Most of the dosage was in the waste jar
 - Manufacturer could not determine root cause

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35.1000 Y-90 Therasphere® Events

- **Two patients received less dose than prescribed**
 - First patient prescribed 72.6 mCi, but received 15 mCi. Inspector thought expansion tubing resulted in turbulent flow triggering suspension issues
 - Second patient prescribed 72 mCi, but received 36.75 mCi – Inspector thought lack of adequate agitation prior to administration or issues with quality/sizing of microspheres
 - Extension tubing no longer used
 - Manufacturer supported Inspector's findings

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35.1000 Y-90 Therasphere® Events

- **Prescribed activity 122 mCi – received 46 mCi – 38% of intended activity**
 - From device components sent to manufacturer no cause for the blockage was determined
 - Obstruction/blockage located in microcatheter - obstruction in the outlet tubing at the E junction
 - Manufacturer recommended handling microcatheters with extra care and looking for kinks

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35.1000 Y-90 Therasphere® Events

- **Prescribed 12,000 cGy – received 2,000 cGy (rad)**
 - Malfunction in the administrative set – significantly less pressure than usual to press syringe
 - Saline accumulating in overflow vial
 - Only returned portion of administration set that infused dosage into patient to manufacturer
 - May have been a kink or obstruction in treatment catheter but not conclusive
 - Will send complete administrative set next time

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35.1000 Y-90 Therasphere® Events

One licensee – 2 reported medical events

- **Report 1 - Prescribed 64.8 mCi, but received 41 mCi - 65% of activity**
 - Air bubbles noted in overflow tubing connected to the micro-catheter
 - Connected 3-way stopcock between overflow tubing and micro-catheter aspirated bubbles to syringe with stopcock close to patient
 - Resurvey of delivery kit showed residual activity

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35.1000 Y-90 Therasphere® Events

- **Report 2 - Prescribed 46 mCi but received 27 mCi – 59% of activity**
 - Used left radial artery with 5-French Sarah Radial catheter with coaxial micro-catheter
 - Nothing unusual was encountered
 - No radioactive contamination of the suite
 - Dose was in catheter, gauze, dose vial and other waste

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35.1000 Y-90 Therasphere® Events

- **Prescribed 89,200 cGy, but received 57,500 cGy - 64% of dose**
 - Backflow of microspheres into contrast line and syringe
 - Significant contamination in contrast syringe, flushing syringe, contrast tubing, and associated y-adaptor
 - Thought contrasting syringe and tubing were made of materials that bind microspheres more than administration kit - will look for same materials
 - Will use clamp and one-way valve

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35.1000 Y-90 Therasphere® Events

- **Prescribed 23 mCi, but received 7.4 mCi – 32% of the activity**
 - Blockage occurred in the delivery apparatus
 - Imaged the administration set and saw most of the undelivered activity near where plunger connects to the dose vial
 - Will send administration set and procedure waste to contractor for manufacturer

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35.1000 Y-90 Therasphere® Events

- **Prescribed 35 mCi, but received 5.4 mCi – 16% of activity**
 - Microspheres were coagulated in the tubing
 - Unexpected activity remained near the Touhy-Borst connector
 - Manufacturer thought caused by issues with the micro-catheter
 - Will flush micro-catheter immediately prior to connecting it to the administration kit

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35.1000 Y-90 Therasphere® Events

- **Prescribed 13,000 cGy to left lobe of liver, but received 8,490 cGy - 65% of dose**
 - First vial administered without incident
 - Second vial primed and prepped, but saw a train of bubbles in the line between the dose vial and patient
 - AU stopped the procedure; did not want the bubbles to cause the flow to reflux into gastric artery and cause permanent damage to the stomach
 - Could not pinpoint cause of bubbles
 - Limit number of staff trained to prime and do set-up and ensure enough are available on treatment days

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35.1000 Y-90 Therasphere® Events

- **Prescribed 24,500 cGy, but administered 13,083 cGy - 53% of dose**
 - CT scan verified dose was administered to correct location
 - Remainder of dose hung up in catheter despite flushing
 - Catheter tubing met manufacturer's specifications
 - No root cause identified

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35.1000 Y-90 Therasphere® Events

- **Prescribed 1,300 cGy to specific part of liver, but received 931 cGy - 71% of dose**
 - Used 3 different written directives to fractionate the delivery
 - Thought the small activity prescribed contributed to under dose because of typical losses in the valve and tubing
 - Order higher dosages for any administration below 10 mCi
 - Amend license to go to different manufacturer

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35.1000 Medical Events

SirSphere®	7
– Wrong site	2
– Measurement unit error	1
– Written Directive error	1
– High activity clogging	1
– Low activity administration	1

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35.1000 Y-90 SirSphere® Events

- | | |
|-----------------------------|---|
| Wrong treatment site | 2 |
|-----------------------------|---|
- **Prescribed 38.4 mCi to liver but received about 13 mCi to abdominal wall**
 - Post-treatment scan appeared normal with small uptake in bowel
 - Pain in abdomen with erythema on abdomen – thought dose was above 55 cGy but less than 1,000 cGy
 - Thought one-third of dose migrated up a venous ligament and lodged in abdominal wall

55*

35.1000 Y-90 SirSphere® Events

- | | |
|-------------------------------------|--|
| Wrong treatment site (cont.) | |
|-------------------------------------|--|
- Difficult visualizing arterial access to the tumor
 - Micro-catheter was not advanced far enough into correct artery
 - Pre-existing kidney impairment precluded using more contrast
 - Add second monitor to refer to original arteriogram without switching tasks and improve confidence of correct location
 - Take prophylactic measures for future patients with impaired kidney function

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35.1000 Y-90 SirSphere® Events

Wrong site

- Prescribed 4,874 cGy to right lobe of liver, but received 11,080 cGy to left lobe
 - Human error
 - Placed catheter in left hepatic artery instead of right hepatic artery

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35.1000 Y-90 SirSphere® Events

Measurement Unit Error

- Prescribed 0.91 GBq, but received 8.9 mCi
 - Ordered 0.91 mCi - marked wrong box in computer
 - Did not multiply measured dose value by correction factor of 10
 - Not identify until post-procedure check
 - Worksheet revised to be in SI units
 - Written directive sheet to be in SI units
 - Dose preparation and post-procedure forms to be in SI units

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35.1000 Y-90 SirSphere® Events

Written Directive Error

- Prescribed 1,504 cGy to right lobe of liver, but received 1,498 cGy in left lobe
 - Written directive prepared incorrectly - AU wanted to treat left lobe
 - Identified after completion of the procedure
 - AU did not indicate correct treatment site on written directive; AU did not forward pre-treatment information to the RSO
 - Clinical staff failed to identify discrepancy during patient time-out just before the implantation

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35.1000 Y-90 SirSphere® Events

High activity clogging

1

- Prescribed 4,320 cGy, but received 828 cGy – 19% of the dose
 - Micro-catheter clogging due to unusually large number of microspheres being used
 - Prescribed activity was at high end of the treatment range
 - Patient administration delayed 1 day - 25% increase in number of microspheres were needed to deliver the dose
 - Will use smaller aliquots and/or slower infusion rate

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35.1000 Y-90 SirSphere® Events

- Device malfunctioned** **1**
- **Prescribed 32.5 mCi but received 8 mCi – 25% of activity**
 - Treatment device malfunctioned and ceased to deliver microspheres
 - Manufacturer's representative was present, but cause of malfunction is unknown
 - Will return delivery device to manufacturer for technical analysis and root cause determination

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35.1000 Y-90 SirSphere® Events

- **Prescribed 19.6 mCi to left lobe of liver, but received 10 mCi – 51% of activity**
 - Planned to deliver activity in two split dosages
 - Written directive not properly reviewed, so split one dosage in two instead of the total dosage in two
 - Radiation oncologist failed to check the drawn dosages prior to injecting them
 - Identified after injection when the remainder of the dosage was discovered

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35.1000 Y-90 SirSphere® Events

- **Prescribed 19.6 mCi to left lobe of liver, but received 10 mCi – 51% of activity (cont.)**
 - Lack of comprehension of dose draw worksheet
 - Miscommunication and failure to review the written directive
 - Failure to perform a safety pause and properly review the dosage to be administered against the written directive prior to the administration

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Acronyms

- AU – Authorized User
- cGy – centiGray
- FY – Fiscal Year
- GBq – Giga Becquerel
- HDR – High Dose Rate Remote Afterloader
- I-131 – Iodine-131
- I-124 – Iodine-124
- IVB – Intravascular Brachytherapy
- Ra-223 – Radium-223
- MBq – Mega Becquerel

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Acronyms

- μCi – microcurie
- mCi – millicurie
- MIBG - Metaiodobenzylguanidine
- Pd-103 – Palladium-103
- RSO – radiation safety officer
- SI units – International System of Units
- Y-90 – Yttrium-90

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QUESTIONS?

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