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United States Nuclear Regulatory Commission
Protecting People and the Environment

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**

	FY13	FY14	FY15
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 2016**
- **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)

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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

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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 preceding
  - 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

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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

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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

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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

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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

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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

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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

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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?