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Protecting People and the Environment

Status of Medical Events FY 2017

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March 7, 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 2012-14

- **48 Medical events reported - FY 2012**
- **43 Medical events reported - FY 2013**
- **46 Medical events reported - FY 2014**

	FY12	FY13	FY 14
35.200	2	0	1
35.300	2	2	3
35.400	15	15	5
35.600	13	10	10
35.1000	20	16	27

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Medical Events 2015-17

- **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(31)	30	24

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Medical Events 2017

35.300 Medical events **4**

Iodine 131	3
Radium 223	1

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35.300 Medical Events (cont.)

Iodine-131 **3**

- **Administered 2 mCi when none was prescribed.**
  - Prescribed parathyroid test but received thyroid scan.
  - I-131 ordered without written directive.
  - Electronic ordering and records system used without confirmation of the order prior to administration.
  - Thyroid received 1,630 cGy.
  - Modified procedures, confirm dosage orders, and re-trained personnel.

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35.300 Medical Events (cont.)

Iodine-131 cont.

- **Administered 20.2 mCi instead of 30 mCi in written directive.**
  - Written Directive was incorrect.
  - Intended dose was given.
  - Three individuals now review the Written Directive for accuracy before signing and administration.

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35.300 Medical Events (cont.)

Iodine-131 cont.

- **Administered 106 mCi instead of 150 mCi.**
  - Dosage delivered in two capsules.
  - Patient shook the vial contents into her mouth, only swallowed one capsule, other left in vial.
  - Discovered when capsule returned to the pharmacy.

8

35.300 Medical Events (cont.)

Ra-223 dichloride 1

- **Administered 176.1 µCi instead of 108.4 µCi.**
  - Wrong patient.
  - Two patients scheduled for Ra-223 treatment on the same day.
  - Doses properly labeled with patient names on the lead pigs and syringes.
  - Wrong syringe used without checking patient identity.
  - Added a timeout, dosing physician verifies identity of the patient and prescribed dose in the written directive.

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Medical Events 2017

35.400 Medical events 7

Prostate 7
- One licensee 2 reports 2
  - Human error
  - Anatomy
- Wrong site 1
- Used previous activity 1
- Larger then pre plan or swelling 3

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35.400 Medical Events

Prostate 7

- **One licensee, 2 separate reports**
- Case 1 - Patient received 62% of the prescribed D90 dose of 14,500cGy.
  - No root cause but attributed to human error.
  - Some seeds may have migrated post implant.

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35.400 Medical Events

- Case 2 - Patient received 78% of the prescribed D90 dose of 14,500 cGy.
  - Caused by patient anatomy.
  - Identified during post-implant CT scan and subsequent dosimetric analysis.
  - Delay in reporting to State due to communication breakdown and inadequate procedures.

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35.400 Medical Events cont.

- **Patient received 2,760 cGy instead of 11,000 cGy 74.9% less than prescribed.**
  - Wrong site.
  - Estimated dose to the urethra at 2,602 cGy (rad), the rectum at 861 cGy, and the penile bulb at 8,689 cGy.
  - human error - additional training to personnel and improved supervision.

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35.400 Medical Events cont.

- **Patient received 157.81% of the prescribed D90 dose of 12,500 cGy – Pd-103 seeds.**
  - Failed to enter correct activity per seed into physics spreadsheet that contained a value from the previous calculation.
  - Did not perform independent verification of treatment data.
  - New action: secondary hand calculation, require use of blank spreadsheet template, and verbal time-out to verify key parameters prior to treatment.

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35.400 Medical Events cont.

- **Prescribed 14,400 cGy received 73% of the dose.**
  - 18% increase in prostate size compared to the pre-plan and the planned intentional cooler coverage near the patient's rectum.
  - Discovered during a routine audit conducted by a medical physicist.

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35.400 Medical Events cont.

- **Prescribed 14,500 cGy received 10,000 cGy - 69% of the dose.**
  - Administered 12/7/2016, event discovered on 12/8/2016.
  - Second treatment on 12/9/2016 - eight more seeds implanted.
  - Post-operative swelling and seed migration
  - Perform post-implant imaging sooner to minimize the effect of swelling of the prostate gland and possible migration of the seed

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35.400 Medical Events cont.

- **Prescribed 14,500 cGy received 10,353 cGy - 71% of the dose.**
  - Order additional seeds beyond what the pre-plan requires.
  - Perform post-implant x-ray and ultrasound to determine if/where additional seeds could be placed.

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Medical Events 2017

35.600 Medical events **8(15)**

HDR

- Gynecological(14) 7
  - Software Issue (9 patients) 2
  - Wrong site 4
  - Equipment failure 1

Gamma Knife 1

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35.600 HDR Events (cont.)

Gynecological **7 (14)**

- **Generic Software issue (4 patients)**
  - Oncentra software versions 4.5, 4.5.1, and 4.5.2 issue with source step size with ring.
  - Source step size of 5 mm instead of 2.5 mm.
  - Dose to unintended site 2,800 cGy to 1,400 cGy.
  - Dose to the unintended site expected too be 126 to 175 cGy per fraction.
  - Elekta notified software users of problem with ring.

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35.600 HDR Gynecological (cont.)

- **Generic Software issue cont. (5 patients)**
  - Oncentra software versions 4.5.2 issue with source step size with ring of 5 mm instead of 2.5 mm.
  - Dose to treatment site 24.46%, 21%, 31.96%, 25.58%and 20.89% less than intended.
  - Did not calculate dose to the unintended site.
  - Some source paths extended beyond planned endpoint and started on a return path back into the lower vagina.
  - Some tissue protection by fluid-filled sleeve that provided some shielding and displacement.

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35.600 HDR Gynecological (cont.)

- **Wrong site** **4**
  - 5 cm site received 500 cGy
  - Wrong software orientation selected.
  - Oncentra treatment planning – must choose if the treatment catheters are modeled from the tip or connecting end of the catheter.
  - Catheter in the tip end mode which was incorrect.
  - Provide additional training to personnel.

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35.600 HDR Gynecological (cont.)

- **Wrong Site cont.**
  - Capri applicator inserted into the patient's rectum instead of vagina on 2nd of 5 fractions.
  - Treatment site received prescribed dose of 350 cGy (rad) during the second treatment.
  - Radiologist confirmed the patient's rectum had been treated.

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35.600 HDR Gynecological (cont.)

- **Wrong site cont.**
  - 5 cm site received 500 cGy
  - first two tandem and ovoid treatments were delivered as prescribed
  - Incorrect tandem applicator length of 119.8 cm was entered into the treatment planning system for third fraction instead of the prescribed 131.9 cm.

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35.600 HDR Gynecological (cont.)

- **Wrong site cont.**
  - Received 700 cGy
  - Physicist determined inserted length of the transfer guide tube was 7.5 cm shorter than intended.
  - The transfer tube was deformed and added pressure needed to fully insert it into the applicator.
  - Removed the transfer guide tube from service, got different design.
  - Counseled staff on the event.

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35.600 HDR Gynecological (cont.)

- **Equipment failure.**
  - Received 6.4% of prescribed 500 cGy dose during the 1st of 5 fractions.
  - Five separate interlocks were tripped in 1st fraction.
  - fluid in the catheter may have contaminated the source and afterloader unit.

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35.600 Gamma knife 1

Gamma Knife Model C.

- **Prescribed 2000 cGy received 1540 cGy to brain lesion**
  - Three of five shots delivered.
  - Couch retracted from the treatment position due to a clutch malfunction.
  - Patient was released - repairs completed in six hours.
  - Patient elected to not return.

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Medical Events 2017

35.1000 Medical events	**24**
Intervascular Brachytherapy	**1**
Y-90 Microspheres	**23**
Therasphere ®	15
SirSphere ®	8

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35.1000 Medical Events

Intravascular Brachytherapy 1

- Prescribed dose of 1,840 cGy (rad) for in-stent restenosis in two dwell positions.
- Received 50% of dose – one position treated.
- Source train stuck - not retract to the afterloader.
- Deformation 7.3 cm distal to the strain relief - located outside the patient.
- Compression of the catheter during a challenging advancement into a commonly tortuous vessel (left internal mammary artery).

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35.1000 Medical Events

Y-90 Microspheres		23
Therasphere ®		15
– Over dose	3	
– Wrong site	2	
– Kinked catheter	4	
– Cracked catheter	1	
– Partial Obstruction	1	
– Leaking connection	2	
– Slow infusion	1	
– Reflux to other lobe	1	

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35.1000 Therasphere® Y-90 Events

Overdose **3**

- **Prescribed 11,000 cGy administered 54,000 cGy - right lobe**
  - Wrong calibration date (6/11/2017 instead of 6/4/2017) used in ordering.
  - Used dose calibrator – did not question results.
  - Written directive not prepared and not signed before administration.
  - Shunting lung dose 2,576 cGy (rad), - intended 524 cGy (rad).
  - About 6 months later no clinically significant symptomatic complications.

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35.1000 Y-90 Therasphere® (cont.)

Overdose cont.

- **Prescribed 34,000 cGy administered 80,800 cGy – liver volume.**
  - Administered before microspheres decayed to the prescribed activity - Scheduling nurse used the pre-treatment plan instead of the final treatment plan.
  - The physicist's pre-treatment calculations and time-out failed.

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35.1000 Y-90 Therasphere® (cont.)

Overdose cont.

- **Prescribed 34,000 cGy administered 80,800 cGy – liver volume.** (cont.)
  - Spreadsheet to calculate patient dose modified to check the administration vial's calibration activity and date versus the prescribed activity and procedure date.
  - The time-out procedure modified to confirm the proper activity prior to administration.

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35.1000 Y-90 Therasphere® (cont.)

Overdose cont.

- **Prescribed activity 1.05 GBq (28.37 mCi) - administered activity was 2.05 GBq (55.35 mCi).**
  - Human error in converting activity from GBq to mCi.
  - Corrective actions - procedure modifications, written directive revisions, and software updates to assist in unit conversions.

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35.1000 Y-90 Therasphere® (cont.)

Wrong site **3**

- **Prescribed 6,000 cGy – administered 4,860 cGy (rad) to the left lobe and 3,650 cGy (rad) to the right lobe.**
  - Challenging anatomy - a narrow window just distal to vasculature suppling right lobe – reflux to right lobe.
  - Verified catheter position multiple ways before administration - no apparent complications.
  - Bremsstrahlung imaging showed microspheres in both lobes.

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35.1000 Y-90 Therasphere® (cont.)

Wrong site

- **Prescribed 6,000 cGy – administered 4,860 cGy (rad) to the left lobe and 3,650 cGy (rad) to the right lobe.** (cont.)
  - Movement of the catheter from unnoticed patient movement (breathing) or angiographically undetected reflux caused by the difference in flow dynamics of the microspheres, contrast agent and Tc-99M macro-aggregated albumin (MAA).

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35.1000 Y-90 Therasphere® (cont.)

Wrong site cont.

- **Two separate segments in the right lobe - prescribed 25.6 mCi to the small segment and 64.3 mCi to the large segment.**
  - Later discovered only 10.27 mCi was ordered for the large segment.
  - Each dose needed different calibration dates.
  - Contrary to vendor guidance, the licensee used one order sheet for the two doses with one calibration date

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35.1000 Y-90 Therasphere® (cont.)

Wrong site cont.

- **Two separate segments in the right lobe prescribed 25.6 mCi to the small segment and 64.3 mCi to the large segment.** (cont.)
  - Process involved several hand-offs, reviews, and verifications by different providers using different source documents - inconsistency between the written directive and the order and assay data was not identified prior to patient treatment.

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35.1000 Y-90 Therasphere® (cont.)

Wrong site cont.

- **Prescribed 47.03 mCi to the left lobe - administered 46.22 mCi to right lobe (right lobe to be treated one month later).**
  - Interventional radiologist and radiation oncologist authorized user signed off on the planned activity for the left lobe via the left hepatic artery - the authorized user completed the written directive.
  - Interventional radiologist put catheter in patient's right hepatic artery for right lobe – human error confused about later treatment of right.

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35.1000 Y-90 Therasphere® (cont.)

Wrong site cont.

- **Prescribed 47.03 mCi to the left lobe - administered 46.22 mCi to right lobe (right lobe to be treated one month later).** (cont.)
  - In operating room time-out all parties confirmed the procedure, and treatment was administered.
  - Modified written directive time out procedure.

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35.1000 Y-90 Therasphere® (cont.)

Kinking 4

- **Prescribed 146.51 mCi - administered 11.35 mCi – liver dose of 970 cGy (rad) and lung dose from shunting of 101 cGy (rad).**
  - Thought slow injection flowrate, dent in the outlet tubing from a pinch-clamp, and over-tightening of the Touhy-Borst Y-adaptor caused sedimentation of the microspheres in the delivery system.
  - The manufacturer's inspection a small mass of microspheres inside the dose vial and within the outlet tubing, multiple locations with kinks, no septum fragments or other obstructions were observed, no evidence that the Tuohy fitting was over tightened.

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35.1000 Y-90 Therasphere® (cont.)

Kinking cont.

- **Prescribed 12,000 rad – administered 6,000 rad.**
  - A kinked delivery catheter prohibited complete microsphere administration.
- **Prescribed 51.57 - administered 39.07 mCi to the right lobe.**
  - Residual activity 12.5 mCi remaining in the delivery device.
  - Visual kink at the hub of the catheter was identified.

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35.1000 Y-90 Therasphere® (cont.)

Kinking cont.

- **Prescribed 46 mCi administered 20 mCi.**
  - Two separate liver segments.
  - Second acrylic jar contained 56% of the microspheres intended for the patient's second liver segment.
  - Protocols for dose preparation, box construction, and dose administration were followed.
  - Minor resistance during the flush of the stretched out micro-catheter.
  - Possible micro-catheter had a kink and be able to flush contrast and saline through it, but have microspheres clog it.

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35.1000 Y-90 Therasphere® (cont.)

Cracked catheter 1

- **Prescribed two doses with a total activity of 54 mCi to the right and left lobes - administered 21.62 mCi**
  - first dose and second administrations through the radial artery of the left hand using a microcatheter (Marksman).
  - Post radiation surveys both about 5 mR/hr for the microsphere vial - AU assumed first was from contaminated cloth but recognized second meant two under doses.
  - Visual inspection of the microcatheter revealed a crack - the crack was determined to be the cause of the event.

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35.1000 Y-90 Therasphere® (cont.)

Partial obstruction 1

- **Prescribed 47.88 mCi – administered 13.91mCi.**
  - Thought treatment went as planned, no issues with viewed flow before administration, no increased resistance was noted and could flush the line post administration.
  - Discovered during survey of waste and performing the dose assessment.

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35.1000 Y-90 Therasphere® (cont.)

Partial obstruction 1

- **Prescribed 47.88 mCi – administered 13.91mCi.**
  (cont.)
  - Thought partial obstruction in catheter or line connecting the microsphere vial to the catheter, vasculature was complicated and may have resulted in movement of the micro-catheter slightly forward from initial placement.
  - Greater than usual amount of saline in the overflow vial.

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35.1000 Y-90 Therasphere® (cont.)

Leaking catheter connection 2

- **Prescribed 11.87 mCi – administered 8.34 mCi.**
  - During treatment liquid leaking from the connection between the e-line and the catheter placed in the patient was noted.
  - Treatment stopped and started decontamination - patient's thigh and groin, skin dose was calculated to be 1.1 μSv (0.11 mrem).
  - Incident due to human error - poor connection between the e-line and the patient's catheter.

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35.1000 Y-90 Therasphere® (cont.)

Leaking catheter connection cont.

- **Prescribed 25.95 mCi – administered 8.99 mCi.**
  - Leak occurred while connecting the infusion line from the microsphere vial to the microcatheter.
  - Physician simultaneously unclamped the administration line while trying to connect it to the microcatheter.
  - Physician assumed the leaking fluid only contained saline and proceeded with administration.
  - Leak caused contamination of the administration area, which was immediately decontaminated.

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35.1000 Y-90 Therasphere® (cont.)

Slow injection rate 1

- **prescribed 175.7 mCi – administered 43.24 mCi.**
  - Slow injection rate to prevent reflux into adjacent gastric artery that could not be coil embolized.
  - Completed administration, three saline flushes, verified digital radiation dosimeter was reading 0.0, indicating that the microspheres had left the vial.
  - Microspheres collected in the catheter outside of the patient.

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35.1000 Y-90 Therasphere® (cont.)

Slow injection rate **1**

- **prescribed 175.7 mCi – administered 43.24 mCi.** (cont.)
  - External experts confirmed that a slow injection rate can result in an event like this and RSO identified catheter backup in another slow injection rate administration.

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35.1000 Y-90 Events (cont.)

SirSphere ® 8

- Labeled vial shield not vial 1
- Low activity administration 3
- High activity clogging 1
- Clogging issues 3
  - Needle 1
  - Catheter defect 1
  - Kinked 1

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35.1000 Y-90 SirSphere ® (cont.)

Labeled vial shield not vial **1**

- **Prescribed 2.453 mCi to small lesion and 22.077 mCi to large lesion - administered 22.077 mCi to small lesion.**
  - Prepared two vials, labeled each vial shield, did not label the vials.
  - Provided vial with 22.077 mCi for small lesion realized mistake when started large lesion.
  - Require time-out, label both the vial and vial shield, read labels three times before administration.

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35.1000 Y-90 SirSphere ® (cont.)

Low activity administration **3**

- **Prescribed 6.49 mCi to 2 segments - administered 4.46 mCi.**
  - Activity in residual waste - stasis was not reached during administration.
  - Procedure modifications, form modifications, written directive adjusted to tighten up the dose drawn to match 100% of the prescribed dose, and committed to have an AMP physician present to observe low activity administrations.

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35.1000 Y-90 SirSphere ® (cont.)

Low activity administration cont,

- **Prescribed 5.49 mCi - administered 4.07 mCi.**
  - Cause of the event was the amount of activity delivered; the relatively low prescribed dose made the residue look comparatively large.
  - Another doctor will supervise the remainder of the administrating doctor's cases - part of the requirements for obtaining authorized user status.

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35.1000 Y-90 SirSphere ® (cont.)

Low activity administration cont,

- **Prescribed 4.05 mCi - administered 3.14 mCi.**
  - Radiation survey revealed residual activity of 1.06 mCi remained in the treatment device.
  - The use of small doses will be carried out after greater scrutiny and review.

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35.1000 Y-90 SirSphere ® (cont.)

High activity clogging 1

- **Prescribed 84.12 mCi - administered 59.8 mCi.**
  - Tubing became clogged and the entire activity could not be administered.
  - Due to a large dose of microspheres - increased amount of microspheres in the system clogged the micro-catheter towards the patient.

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35.1000 Y-90 SirSphere ® (cont.)

Clogged needle 1

- **Prescribed 32.97 mCi - administered 8.2 mCi.**
  - Occlusion of the vial delivery C needle due to clumping of the microspheres.
  - Intended to return to manufacturer but discarded after activity decayed to background.
  - Educating the administrator of the microspheres on how to clear the clogged needle, which is to reverse the valve for flushing purposes.

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35.1000 Y-90 SirSphere ® (cont.)

Catheter defect 1

- **Prescribed 12.16 mCi - administered 5.64 mCi.**
  - AU and interventional radiologist noticed a strong resistance as they pushed on the syringe.
  - The micro-catheter was pulled from the patient - a very small defect was observed.
  - Cause of the microsphere blockage was a defect in the micro-catheter.
  - MedWatch FDA Adverse Event form completed.

35.1000 Y-90 SirSphere ® (cont.)

Kinked catheter 1

- **Prescribed 40.4 mCi - administered 21.5 mCi.**
  - Think patient inhaled deeply and created a kink in the catheter.
  - The first three or four aliquots were delivered before the plunger met resistance.
  - Kinked catheter was confirmed by PET/CT imaging of the administration set and vial.

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
- Ra-223 –Radium-223
- mCi – millicurie
- µCi – microcurie
- MBq – Mega Becquerel

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QUESTIONS?