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

Status of Medical Events FY 2019

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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.

2

Medical Events FY 2014 - 2016

- **46 Medical events reported - FY 2014**
- **57 Medical events reported - FY 2015**
- **50 Medical events reported - FY 2016**

	FY14	FY15	FY16
35.200	1	3	4
35.300	3	8	4
35.400	5	9(10*)	6 (18)
35.600	10	17	6
35.1000	27	20(30)	30

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

3

Medical Events FY 2017 - 2019

- **43 Medical events reported - FY 2017**
- **48 Medical events reported - FY 2018**
- **56 Medical events reported - FY 2019**

	FY17	FY18	FY19
35.200	0	0	1(8)
35.300	4	2	9
35.400	7	11(13)	5
35.600	8 (14)	10	9(10)
35.1000	24	25(26)	32

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Medical Events 2019

35.200 Medical events	**1**
Sr-82/Rb-82 Generator	1 (8)

5

35.200 Medical Events

Sr-82/Rb-82 Generator **1**

- **8 patients - 100.7 to 256.9 cGy (rad) to the red marrow, 117.12 to 299.36 cGy (rad) to the bone surface, and 27.02 to 68.4 cGy (rad) effective dose.**
  - Excess Sr-82 and Sr-85 breakthrough for 3 days.
  - Breakthrough test performed by three different individuals, each recorded no breakthrough values.
  - Unknowingly eluted generator on day one with Ringer's Lactate.
  - Discovered from unexpected waste survey results.

6*

Sr-82/Rb-82 Generator (cont.)

- Primary Failures
  - Human error in the inadvertent use of Ringer's Lactate to elute the Rb-82 generator.
  - Inadequate practices in conducting the QC strontium breakthrough analyses.
- Corrective Actions
  - Immediately stopped the Rb-82 generator program.
  - Automated medication dispensing system with medication scanning prior to each administration.
  - Daily audits of the IV fluid, modify the forms, obtain new equipment, and train personnel.

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Medical Events 2019

35.300 Medical events		**9**
Iodine -131	3	
Na I-131	2	
I-131 Iomab-B	1	
Samarium-153	1	
Radium-228	2	
Lutetium-177	3	

8

35.300 Medical Events

NaI-131 **2**

Liquid I-131 - spill from feeding tube **1**

- Administered 2.73 GBq (73.8 mCi) of prescribed 6.48 GBq (175 mCi) of liquid I-131.
- Patient unable to swallow pill, so administered through a feeding tube inserted into the patient's gastric tube.
- Pool of radioactive liquid next to the patient on a disposable drape, on the patient, and on the imaging table after flushing the feeding tube with saline.
- Feeding tube removed from the gastric tube and flushed, no further leakage.

9*

35.300 NaI-131 Spill (cont.)

Spill from feeding tube (cont.)

- Spill contained; patient and site decontaminated; no hospital personnel contaminated.
- Determined spill activity 3.74 GBq (101.2 mCi) by surveying all contaminated items in storage drum and conservative decay calculations.
- Concluded cause was a feeding tube failure.
- Do not plan to perform any more administrations of I-131 through a feeding tube.

10

35.300 Na I-131 Capsule

Wrong patient **1**

- **Prescribed 0.518 GBq (14 mCi) [40,000 cGy (rad)] for hyperthyroidism, but administered 1.221 GBq (33 mCi) [96,500 cGy (rad)].**
- The wrong I-131 capsule was administered - did not verify it was for the patient.
- Techs were re-educated on the importance of following procedures for administration of radiopharmaceuticals.

11

35.300 I-131 Iomab-B

I-131 Iomab-B **1**

- **Administered 17.13 GBq (462.92 mCi) I-131 Iomab-B 42% less than prescribed 29.415 GBq (795 mCi).**
- Clinical trial for acute myeloid leukemia - used delivery system under research and development.
  - Delivery system design was cause - it did not permit visualization of the dosage vial and required the manufacturer to set the infusion time.
  - Manufacturer was present and assisted in setting up the delivery system and infusion time.
- Refused to continue in trial until development of a system with visualization of the dose.

12

35.300 Sm-153 Leak

Sm-153 Quadromet 1

- **Administered 86.95 MBq (2.35 mCi) but prescribed to 2,146 MBq (58 mCi).**
- Sm-153 leaked – initially thought a crack in the locking assembly of the IV tubing caused the leak.
- Concluded from location of the spill that IV tubing itself failed.
  - Abraded at the time of needle insertion.
  - Added pressure from the dosage administration caused the tube wall to fail and the leakage.

13

35.300 Ra-223 Xofigo

Ra-223 Xofigo 2

Incorrect written directive 1

- **Administered 3.07 MBq (83 µCi) per but standard dosage protocols that was dispensed correctly by the pharmacy and administered to the patient.**
- Licensee assayed dosage vial using an incorrect setting on the dose calibrator – displayed dosage of 2.07 MBq (56 µCi).
- The written directive filled out according to the incorrectly assayed dosage resulting in incorrect written directive.

14*

35.300 Ra-223 Written Directive (cont.)

Incorrect written directive (cont.)

- Future written directives will receive the physician's signature and approval prior to assaying the dosage.
- Discovered during a routine written directives audit.
- Written directives will be audited quarterly by the RSO or designee.

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35.300 Ra-223

Received half of 2 administration

- **Prescribed 8.65 MBq (233.69 µCi) of Ra-223 Xofigo, received 4.41 MBq (119.19 µCi)**
- Dosage was divided into 2 syringes - size of the patient and doses typically arrive in 10 cc syringes.
- After first syringe, patient was discharged.
- Patient returned the following day and received the second syringe of 4.24 MBq (114.5 µCi).
- Corrective actions included additional training and supervision to personnel.

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35.300 Lu-177 Lutathera

Lu-177 Lutathera 3

Infusion pump issue

- **Prescribed 7.4 GBq (200 mCi) of Lutathera, received 4.99 GBq (134.9) - 32.55% of dosage**
- Infusion method had potential for small bubbles to develop in the infusion line, causing the pump to alarm.
- Technologist was aware of issue, knew how to prevent it, called away, and instructed the other technologist to pause the infusion and contact her if the pump alarmed.

17*

35.300 Lu-177 Infusion Pump Issue (cont.)

- Pump alarmed - other technologist tried to restart - a larger bubble formed in the line.
- Nurse asked to assist in purging the line but drained Lu-177 into an emesis basin, thinking it was saline.
- Contaminated staff and patient clothing, and areas of the treatment bay; clothing held for decay and treatment bay decontaminated.
- Make-up dose administered the next day to complete the patient's planned therapy.
- Retraining applicable staff members and modifying the Lu-177 infusion method.

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35.300 Lu-177 Lutathera

Vial Issue 1

- **Administered 5.39 GBq (145.7 mCi) of Lu-177 intended 7.4 GBq (200 mCi)**
- Loss of integrity of the air seal on the Lutathera vial caused the fluid level to rise within the vial.
  - Positive pressure cap on the peripherally inserted central catheter (PICC) offered resistance to the flow, and led to the fluid level rise in the vial.
  - Height of the vial possibly too low relative to the entry point in the patient, affecting gravity influence on the flow.

19*

35.300 Lu-177 Vial Issue (cont.)

Corrective actions:

- Written procedures require replacing a positive pressure cap on the line from the vial to the patient with a free-flow cap to reduce backpressure on the line.
- 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
- Revising the written directive form.

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35.300 Lu-177 Lutathera

FDA Protocol and Medical license restrictions 1

- **Intended four treatments of Lu-177 at 7.4 GBq (200 mCi) each to the midgut.**
- Physician changed the dosage of the fourth and final treatment to 3.7 GBq (100 mCi).
  - Per FDA protocol, commercial nuclear pharmacy could only ship full vials of Lutathera at 7.4 GBq (200 mCi).
  - If the physician wanted to administer half the dose, medical facility would have to do it. Medical use RSO informed medical physicist and physician that they were not licensed to split doses.

21*

35.300 Lu-177 Protocol/License Restrictions (cont.)

- Patient agreed to full dosage of 7.4 GBq (200 mCi).
- RSO stated that both the prescribing physician and the patient were notified that the written directive was not updated.
- The highest critical organ doses in excess of the prescribed written directive were the spleen at 304 cGy (rad) and the kidneys at 235 cGy (rad).
- Licensee will consult with the primary physician and update the written directive if the dose in the written directive cannot be provided by the radiopharmacy.
- No adverse effects are expected to the patient.

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Medical Events 2019

35.400 Medical events	**5**
Prostate 5	
One licensee, 2 reports	2
Wrong site	1
Source activity error	1
No post implant procedures	1

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35.400 Medical Events

Prostate **9 (11)**

One licensee, 2 separate reports, 2 patients

- Report 1 - prescribed 10,000 cGy, 82 Pd-103 seeds (59.57 MBq (1.61 mCi) each) to the prostate.
  - Preplanned treatment plan revised periodically during implantation using ultrasound images of seed positions – D90 of 102%.
  - 30 day post implant CT scan dosimetry evaluation D90 was determined to be 74.8% intended dose.
  - Prostate gland larger at the 30-day CT scan compared to the day of the implant (46.4 cm3 vs. 39.7 cm3).
  - Caused post-operative swelling.
  - Identified on inspection.

24*

35.400 One licensee, 2 reports (cont.)

- Report 2 - prescribed 10,000 cGy, 52 Pd-103 seeds (56.6 MBq (1.5 mCi) each) to the prostate
  - Preplanned treatment plan revised periodically during implantation using ultrasound images of seed positions – D90 determined to be 82%.
  - 30 day post implant CT scan dosimetry evaluation D90 was determined to be 62.4% of the intended dose.
  - Cause - post-operative swelling.
  - Identified on inspection.

25

35.400 Wrong Site

Wrong Site

- Prescribed 10,000 cGy (rad) to the patient's prostate gland, 52 seeds (2,486.4 MBq (1.292 mCi each).
  - All implanted inferior to the prostate by 4 cm in penile bulb misread ultrasound image.
  - Discovered 42 days later during the post-implant dosimetry review.
  - The estimated dose to the prostate was 0 cGy (rad) exposure to 90% of the penile bulb was 7,399 cGy (rad).
  - Second implant planned.
  - Cause - human error. Corrective actions included providing additional instruction to personnel.

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35.400 Wrong Activity

Wrong seed activity

- Prescribed an activity of 6.1 GBq (164.85 mCi) for a dose of 14,100 cGy (rad), but was administered 7.89 GBq (213.15 mCi) for a dose of 17,540 cGy (rad)
  - Dosimetrist entered an incorrect source strength (weaker seeds) into the planning system.
  - Total source strength 29% greater than intended and dose 24.4% greater than prescribed.
  - Discovered during post treatment review and CT scan.

27*

35.400 Wrong Activity (cont.)

- Corrective Actions:
  - During receipt and assay, highlight source strength on manufacturer's data sheet.
  - Physician and dosimetrist/physicist will ensure prior to implantation that the correct seed strength is being used and has been input in the planning system.

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35.400 No Procedures

- **No post implant procedures**
  - Prescribed 16,000 cGy (rad) (1.512 GBq (40.875 mCi) I-125), received a dose of 12,070 cGy (rad) or 24.5% less dose.
  - Discovered during inspection.
  - Licensee did not have written procedures for prostate seed therapies that ensure the administrations are in accordance with the written directive.
  - Two other patient records had no post operational dosimetry report.
  - Licensee no longer actively engaged in brachytherapy and the authorized user is no longer with licensee.

29*

35.400 No Procedures (cont.)

- Appropriate nomogram and/or procedures referenced are no longer available.
- Corrective actions:
  - Will ensure that either procedures are established or modality authorization is removed from license.
  - The authorized user moved to another facility and utilized the same procedures.
  - Regulator is following to ensure that procedures are adequate and implemented at that new facility.

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Medical Events 2018

35.600 Medical events **9**

HDR

- Gynecological 9(10)

Device malfunction	1
Wrong site	5
Wrong plan	1
Catheter	1
Unidentified human error	1

31

35.600 Wrong site - Guide Tube

Wrong site - guide tube lengths

- Prescribed 2,400 cGy (rad) to the uterus in three equal fractions using three guide tubes – received 1,600 cGy (rad).
- All three source guide tubes in final fraction were too long (132 cm instead of 120 cm in length) and the entire 800 cGy (rad) was delivered to the vagina.
- The patient returned for monitoring - very mild skin reaction that resolved without any major intervention.

32*

35.600 Wrong site - Guide Tube (cont.)

- Cause - human error
- Corrective Actions:
  - Store the black end guide tubes (120 cm) on the wall and the green end guide tubes (132 cm) on a different rack, instead of the same storage rack.
  - Doctor will also use a ruler to verify the length of the guide tubes before each treatment.

33

35.600 HDR Events

Wrong site - did not correct catheter length

- Prescribed three fractions - intended target receiving 50% of the prescribed 1,400 cGy (rad) and unintended tissue (thighs) received 700 cGy (rad).
- Catheter length should have been 1500 mm, the planner noticed length incorrectly set at 1293 mm and changed the setting to 1500 mm, but failed to press the enter key.
- Plan approved with incorrect setting and first and second fractions completed.
- Another physicist reviewed the plan and discovered the error before third fraction.

34*

35.600 Did Not Correct (cont.)

- Error was due to the failure of the technician to correctly change the distance in the treatment plan.
- Failure of individuals who reviewed the first two treatments to catch the error.
- Corrective Actions:
  - Treatment plan developed to correct the exposure to the intended tissue.
  - Individuals received additional instruction on performing thorough reviews of treatment plans prior to performing a treatment.

35

35.600 Wrong site

- **Prescribed two fractions at 500 cGy (rad) to the vaginal cuff per fraction**.
- In first fraction, a vaginal cylinder was placed in the vaginal canal and the positioning was verified with a cone beam CT scan and cylinder was then connected to the afterloader.
- After completing the treatment, the vaginal cylinder was discovered dislodged from the initial position and between the patient's legs, estimated 500 cGy (rad) skin dose – no erythema at discovery.

36*

35.600 Wrong site (cont.)

- The patient indicated that she had coughed at some point during the treatment, which may have contributed to the dislodgement of the cylinder.
- Corrective actions:
  - Purchasing a more rigorous immobilization device for the applicator.
  - Research/review and update the brachytherapy monitoring procedures and devices throughout the system.

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35.600 Wrong Site - 2 patients

Wrong Site - 2 patients

- Both patients - prescribed 1,000 cGy (rad) to the vaginal cavity across two fractions, but only received 5% of dose at the target area.
- Both received 1,000 cGy (rad) to distal part of the vaginal wall instead of 200 cGy (rad) for first patient and 50 cGy (rad) for second patient.
- Technician entered applicator length of 120 cm into the device console, instead of 125 cm; caused 5 cm offset.

38*

35.600 Wrong Site - 2 patients (cont.)

- Two years earlier, the length of the vaginal applicator changed from 120 cm to 125 cm.
- Corrective Actions:
  - Reorganized applicator and catheter storage – separate cabinet for applicator using different treatment length.
  - Added and posted time out procedure with items to be verified before treatment.
  - Quality Management Program form - added total length of the rigid tube connected to the transfer tube verification and color coded high-risk items

39*

35.600 Wrong Site - 2 patients (cont.)

- Corrective Actions (cont.):
  - Annual review training by physicist for AUs, AMPs, and therapists emphasizing the importance of time out and verifying planned parameters versus delivery parameters and that rigid guide tube and the transfer guide tube total length can differ between applicators.
  - Conducted risk management meeting to further analyze their workflow in place.

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35.600 Applicator Position

Wrong site - applicator position

- Prescribed four fractions - bowel (non-target) tissue received in excess of 50 cSv (rem) and 150% of the expected dose from all fractions.
- Cause - positioned the uterus/ovary applicator in the wrong location on last fractions.
- Intended target tissue received the intended dose in each fraction.
- Did recalculation with larger volume below reporting level.

41

35.600 Copied Wrong Length

Copied wrong length for catheter

- Prescribed 550 cGy (rad) over five fractions for a total dose of 2,750 cGy (rad) to the cervix.
- Using a Syeb-Neblett Template and seven catheters (two being 25 cm in length and five being 30 cm in length).
- Inferior surface of the right vaginal wall (2 cc volume and approximately 5 cm from the cervix) received total of 726 cGy and 236 cGy from later make up treatment - intended to receive 590 cGy (rad) over the five fractions - Difference of 372 cGy (rad) or 63%.

42*

35.600 Copied Wrong Length (cont.)

- Physicist copied the catheter length from one of the 25 cm catheters in first fraction plan and pasted it into two of the 30 cm catheter locations in second, third, and fourth fraction plans.
- Error identified prior to administering fifth fraction.
- Patient ultimately received the full intended dose to the tumor.
- Corrective Actions:
  - Updated procedures to record catheter lengths in a separate document during measurement.
  - No longer use different catheter lengths.

43

35.600 Equipment Failure

Equipment failure - Varian model GammaMed Plus

- Intended to receive the last of three HDR treatment fractions, with a total treatment time of 222.6 seconds divided through eight source positions.
- 25 seconds into the treatment, the HDR unit issued an inactive source error and retracted the source.
- The physicist confirmed that the source had retracted.
- Manufacturer recommended to turn console key off and then back on - failed 25 seconds into reset treatment.

44*

35.600 Equipment Failure (cont.)

- Remaining treatment plan saved.
- Patient - applicator removed and sent home.
- Varian service representative replaced the Geiger Muller board and verified functionality.
- The final portion of the treatment delivered a few days later without incident.
- The patient was informed at the time. The attending physician was notified 6 months later.

45

35.600 wrong treatment plan

Wrong treatment plan 1

- Prescribed 10 fractions of 625 cGy (rad) per fraction for five days (total of 6,250 cGy (rad)) – one fraction received 187% of fractional dose (1,167.3 cGy (rad)).
  - Pretreatment setup - satisfactory, included time out.
  - Test run of the dummy source for clearance of each channel – resulted in "electronic defective" error - treatment was aborted.
  - Physicist confirmed no dose delivered.
- Physicist loaded first treatment plan in the list (not the correct plan), looked at pre-treatment report, and got treatment code needed to start.

46*

35.600 Wrong Treatment Plan (cont.)

- Doctor started treatment – doctor and physicist monitored patient by closed circuit TV but not treatment console.
  - Physicist did not hear the system change to a different channel – looked at treatment console – recognized something was wrong -all the dwell times were in channel one.
  - Physicist stopped treatment; informed doctor of wrong treatment plan.
- Cause – after aborted test there was neither a time out or plan verification and treatment console wasn't monitored.

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35.600 Wrong Treatment Plan (cont.)

- Corrective Actions:
  - 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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35.600 HDR Events

Error not identified

- Prescribed 700 cGy (rad) per fraction - received a total of 467 cGy (rad) in first two fractions - identified before finishing scheduled third fraction.
- Cause - human error.
- Corrective Actions:
  - Amend written directive to give additional fractions to administer original dose to treatment area.
  - Update procedures and providing retraining.

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Medical Events 2018

35.1000 Medical events	**32**
Perfexion	**2**
Intervascular Brachytherapy	**2**
Y-90 Microspheres	**28**
Unidentified	1
Therasphere®	15
SirSphere®	12

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35.1000 Perfexion

- **Perfexion - Head frame slipped 2**
- **First** - patient's head may have slipped forward in the stereotactic frame by two millimeters.
- Collimator collision error during the treatment.
- Treatment halted - patient removed from the gamma knife.
- AU quickly looked at the frame, didn't see anything wrong, and the treatment was resumed.

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35.1000 Perfexion Head Frame (cont.)

- **First** (cont.)
- After the treatment, the neurosurgeon noticed when removing the frame that the frame had shifted.
- Did not know when the slippage happened - dose could be 50% of the prescribed dose if during treatment.
- Licensee intended to use follow-up MRI scheduled 51 days later to help determine if medical event occurred.
- Patient died before the MRI date.

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35.1000 Perfexion Head Frame (cont.)

- **Second** -The planned 2,500 cGy (rad) for 36.8 minute 0.1 cc. trigeminal neuralgia treatment at single position.
- Eight to nine remaining - significant patient movement but complied when asked to hold still.
- 4.04 minutes remaining - treatment stopped when the head fixation frame had shifted.
- Anterior pins almost touching the skin two inches above the original pin sites.

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35.1000 Perfexion Head Frame (cont.)

- **Second (cont.)**
- Estimated doses:
  - Unintended 0.1 cc target volume received approximately four to five minutes of dose or roughly 270 to 340 cGy (rad).
  - The intended treatment site received between 2,230 and 2,160 cGy (rad).
- Incident to be covered in annual training review.
- Elekta contacted to assess possibilities for managing the frame fixation issue.

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35.1000 Intravascular Brachytherapy

Wrong site – same licensee 2

- **First** - prescribed to receive 1,840 cGy (rad) to a coronary artery – received 0. Regulator estimated aorta 60 mm proximal to the intended target received 66 cSv (rem).
- Aborted after attempting to reach treatment site three times.
  - The source train retracted without complication
  - No procedural or regulatory violations and no equipment failures.

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35.1000 Intravascular Brachytherapy

- **First** (cont.) -
- License discussion on general reporting requirements.
  - Desire to classify torturous anatomy as patient intervention.
  - Desire to convert tissue equivalent dose to a whole body effective dose.
- Regulator clarification – agreed the root cause was torturous patient anatomy but disagreed that it is classifiable as patient intervention.

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35.1000 Intravascular Brachytherapy

- **Second** - prescribed 1,840 cGy (rad) to the circumflex artery - received 0. Unintended site received 98 cGy (rad).
- Attempted procedure three times - source stopped 10 mm proximal to the treatment site - junction between the left coronary and circumflex artery.
- Aborted treatment - source retracted - no indication of delivery catheter kinks.

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35.1000 Intravascular Brachytherapy

- **Second (cont.)**
- Root cause:
  - Tortuous patient anatomy
  - Failure to follow procedure of inserting the delivery catheter, then withdrawing the guide wire and then extending it back down the catheter tubing as a "dummy run" to check for restrictions prior to sending the source train.
- Corrective Actions:
  - Additional personnel receiving training and commit to follow previously submitted procedures.

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35.1000 Medical Events

Y-90 Microspheres	**33**
Unknown	1

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35.1000 Unknown Y-90 Events

Unknown **1**

- Received 76% of the planned dose
- Remainder of activity leaked out because of a faulty stopcock assembly.
- The affected area was contained and decontaminated.

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35.1000 Medical Events

Y-90 Microspheres	**28**
Therasphere ®	**15**
– Overdose	3
– Wrong lobe	1
– Air bubbles	2
– Kink	2
– Stasis	1
– Catheter diameter	2
– Calibration date	1
– Equipment failure	3

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35.1000 Y-90 Therasphere® Events

Over dose – no procedures or not followed

- Prescribed 12,000 cGy (rad); Received 69,800 cGy (rad)
  - The correct dose order either was never received by Nordion/BTG or was never ordered.
  - Staff did not properly assay the microspheres in the hot laboratory and did not reconcile it with the prescribed dosage.
  - Dosage was not confirmed prior to administration. Did not perform additional time-out to use the usual time-out checklist in addition to confirming the prescribed and assayed dose to be infused.

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35.1000 Y-90 Therasphere® Events

Over dose – no procedures or not followed (cont.)

- Adequate documentation process did not exist - needed document retention for dose orders.
- 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.
- Dosage assay process and documentation requires two nuclear medicine technologists.
- Enhanced radiopharmaceutical ordering and shipment tracking and reconciliation process.

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35.1000 Y-90 Therasphere® Events

Over dose – no procedures or not followed (cont.)

- Retain all radiopharmaceutical ordering forms and written directives.
- Revise Written directive worksheet to differentiate between prescribed and administered dosage.
- Used patient identifiers in the Nordion/BTG order reference number field.
- Add administered dosage in standard radiology report template.
- Provide training to interventional nursing and associates in post procedural care and radiation safety for microsphere patients.

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35.1000 Y-90 Therasphere® Events

Over dose - wrong patient

- **Prescribed 25,100 cGy (rad) to the liver, recieved 56,200 cGy (rad).**
  - Dose intended for a different patient.
  - Cause: human error
  - Corrective actions: procedural review and revision and personnel retraining.

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35.1000 Y-90 Therasphere® Events

Over dose - vial labeling error

- Two liver lesions - treatment with two vials.
- One vial contained an activity of 7 GBq (189.19 mCi) and the other contained 9 GBq (243.24 mCi).
- Doctor reviewed the treatment records and discovered labeling error and vials may have been switched.
- Smaller lesion received the larger dose and the larger lesion received the smaller dose.

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35.1000 Y-90 Therasphere® Events

Two lobes - dose to wrong one

- Prescribed 584.6 MBq (15.8 mCi) to the left lobe (230 cc volume) and 3,996 MBq (108 mCi) to the right lobe (1,600 cc volume).
- Left lobe's dose was delivered to the right lobe.
- Right lobe received 1,760 cGy (rad) 15 % of prescribed 12,000 cGy (rad) dose.
- Corrective actions: generating a new procedure and providing new training to personnel.

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35.1000 Y-90 Therasphere® Events

Air bubbles

- Prescribed 12,700 cGy (rad), received 5,980 cGy (rad) - 47% of dose.
- Two vials – no issues with first; second was relatively full when returned for disposal and activity higher than expected.
- Physician saw multiple air bubbles trapped in the line After connecting line between the microcatheter and the delivery vial.

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35.1000 Y-90 Therasphere® Events

Air bubbles (cont.)

- Three-way stopcock and syringes used to bleed out air and flush back dose to the patient
  - Prevented spillage or contamination and residual dose was retained in the syringes and stopcocks.
  - Activity remained in delivery equipment and did not go into the patient.
- The root cause: human error.
- Corrective Actions: refresher training and change procedure to confirm no air is not in the line between the microcatheter and the dose vial prior to connection.

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35.1000 Y-90 Therasphere® Events

Air bubbles - possible kink

- Prescribed 1.232 GBq (33.3 mCi) to the right lobe of the liver, received 451 MBq (12.19 mCi) 36% to the right lobe and planned 42 MBq (1.14 mCi) to the lungs.
- No issues with catheter placement, position verification, flow during contrast and normal saline phases,
- Administration started - interventional radiologist saw several small air bubbles in the delivery line, experienced high resistance (saline went into vented vial), and stopped procedure.

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35.1000 Y-90 Therasphere® Events

Air bubbles - possible kink (cont.)

- Used PET scanner to evaluate the activity in patient and delivery system.
- The cause: either a small air pocket or kink in the catheter - delivery system and catheter were sent to the vender for evaluation.
- Corrective Actions: proper setup of the delivery system retraining.
- Procedures modified - to check for air bubble before piercing the dose vial, and perform wet connection when connecting the catheter to the delivery system.

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35.1000 Y-90 Therasphere® Events

First kink

- Prescribed 13,500 cGy (rad), received 4,900 cGy (rad) - 36.3% of dose.
- Not sure if caused by patient stasis or delivery system.
- Authorized user physician had used a thinner micro-catheter (2.4 French Maestro) but manufacturer indicated catheter size commonly used
- Tortuous path caused resistance in the circuit higher than the administration box could tolerate and delivery system could not work properly.
- Concluded problem was not due to patient stasis.

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35.1000 Y-90 Therasphere® Events

First kink (cont.)

- Manufacturer evaluated the Y-90 kit for cause.
  - Microspheres found from outlet tubing to microcatheter.
  - Location of observed kinks had elevated radiation readings.
  - Pressure/Flow tests confirmed set functioned as expected.
  - Septum fragment in the dose vial did not block the flow path.
  - Obstruction within the microcatheter.
- Root cause: obstruction within the microcatheter due to a kink.
- Difficulty placing the catheter before the treatment may have increased likelihood of a kink.

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35.1000 Y-90 Therasphere® Events

Second kink

- Prescribed 12,300 cGy (rad) to segment II of the left hepatic lobe, received 2,950 cGy (rad).
- Back pressure during the treatment with significant flow of saline into the pressure relief vial.
- Procedural images reviewed to look for failure.
  - Catheter was kinked and likely created the blockage.
  - Catheter moved between verification and administration from manipulation of the system connected to the catheter.

74

35.1000 Y-90 Therasphere® Events

Second kink (cont.)

- Delivery system sent to manufacturer for evaluation - no problem identified.
- 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.

75

35.1000 Y-90 Therasphere® Events

Resistance - complex hepatic arterial system (stasis)

- Prescribed 12,000 cGy (rad) to segment four of the left lobe of the liver, received 640 cGy (rad) - 5% of dose.
- All pre-procedural safety checks conducted and appropriate imaging (cone beam CT) performed for catheter position and lesion location.
- High resistance felt on the syringe during the first set of infusions, and continued for the next few infusions.
- Stopped the treatment - risk of inadequate delivery of the microspheres due to possibility of stasis and concern for non-target embolization to other sites.

76

35.1000 Y-90 Therasphere® Events

Resistance - complex hepatic arterial system (cont.)

- PET CT post procedure for microsphere distribution - no non-targeted deposition.
- Undelivered microspheres were in the catheter.
- Licensee concluded incident due to emergent patient conditions and resistance of the patient's complex hepatic arterial system (stasis).
  - No evidence of catheter misplacement.
  - No non-target disposition.
  - No mechanical failure of the microsphere delivery system.
  - No evidence of any non-compliance with NRC guidelines.

77

35.1000 Y-90 Therasphere® Events

Catheter diameter

- Prescribed 2.29 GBq (62 mCi), received 1.37 GBq (37 mCi) 40% of dose.
- Two vials – no issues with first; 51% of second vial microspheres stuck in the catheter.
- Primary cause was equipment malfunction.
  - Catheter and device tubing sent to manufacturer.
  - Manufacturer concluded microspheres remained in the catheter because the catheter used had a internal diameter (0.4 mm) smaller than manufacturer requirements (> or = 0.5 mm).
- Will use larger diameter catheters in future.

78

35.1000 Y-90 Therasphere® Events

Catheter diameter too small

- Prescribed 22,000 cGy (rad), received 10,710 cGy (rad).
  - Particularly tortuous anatomy - after consulting with manufacturer and used a smaller 2.0 Fr catheter.
  - Microspheres stuck in the micro-catheter.
  - Delivery kit and catheter sent to the manufacturer - visual investigation, radioactive measurement, and digital microscope/flow tests - results in line with licensee's initial conclusion.
- Later procedure with larger microcatheter successful.
- Physician will continue to use larger microcatheters.

79

35.1000 Y-90 Therasphere® Events

Calibration date error

- Prescribed 11,000 cGy (rad) to the right lobe, administered 1,790 cGy (rad) - 16% of dose.
  - Administered microspheres with calibration date of 7/28/2019 instead of a calibration date of 8/4/2019.
  - Technologist and AU reviewed the ordering paperwork but failed to identify the incorrect calibration date prior to ordering.
  - Compared the dose activity to the order form instead of the written directive.
  - Used vender provided locked spreadsheet to determine ordering dose but it does not flag when a dose varies significantly from the prescribed dose.

80

35.1000 Y-90 Therasphere® Events

Calibration date error (cont.)

- TheraSphere doses must be ordered in GBq, but licensee is more familiar with mCi; technologist and AU did not recognize that the activity was abnormally low.
- Corrective Actions:
  - Modified the spreadsheet to flag doses not within 10% of the prescribe dose on the day of administration.
  - Technologist and AU will review the written directive and ordering form together prior to administration to ensure that there are no discrepancies with the prescription or dose.

81

35.1000 Y-90 Therasphere® Events

Leak at injector needle/septum interface

- Prescribed 12,000 cGy (rad) to the left lobe of the liver, received 8,090 cGy (rad) - 67.42% of dose.
- Delivery system sent to manufacturer - visual inspection, radiation measurement, digital microscopy, and pressure/flow testing.
  - Microspheres were in the acrylic vial shield indicating a leak at the injector needle/septum interface.
  - Thought to be from product defect - routine administration pressures do not produce this kind of leak.
  - No damage or visible defect was observed on the delivery system or dose vial.

82

35.1000 Y-90 Therasphere® Events

Tubing defect

- Prescribed 20,800 cGy (rad), received 14,500 cGy (rad) 69.7% of intended dose.
- Two vials – no issues with first; second vial failed to empty into the administration catheter further attempts were unsuccessful.
- The vial and administration kit sent to manufacturer for analysis.
  - The tubing had a manufacturing defect that restricted flow and eventually caused the blockage.
  - The defect could not be seen or felt by inspection.

83

35.1000 Y-90 Therasphere® Events

Microspheres tubing/catheter connector

- Prescribed 14,300 cGy (rad), received 5,434 cGy (rad) - 38.5% of dose.
- Dose stayed in the connector of the tubing and catheter.
- Manufacturer tested tubing and catheter; found flow through the catheter insufficient possibly from:
  - Overall length and inner diameter of the microcatheter.
  - Septum fragments from the dose vial.
  - Possible changes from time of treatment to inspection (e.g., dried saline, coiled in tight bends for extended time, etc.).
- AU did not use manufacturer's recommended size microcatheter.

84

35.1000 Y-90 Therasphere® Events

Microspheres tubing/catheter connector (cont.)

- Several potential causes and contributing factors – no definitive root cause.
- Corrective Actions:
  - Continue to follow their standard operating procedure of performing three flushes, ensuring the electronic dosimeter is reading zero, and surveying the patient.
  - Flush an additional time with 20 ml of saline after the electron dosimeter reads zero.
  - Use a catheter with a diameter greater than or equal to 0.02 inches.

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35.1000 Medical Events

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– Equipment	1
– Catheter	5
– No information	1

86

35.1000 Y-90 SirSphere® Events

Wrong site – other lobe and stomach

- Prescribed 1.16 GBq (31.3 mCi) to the right lobe of the liver, received 2,900 cGy (rad) to the right lobe of the liver - 63.2% of the dosage, 2,170 cGy (rad) to the left lobe - 33.5% of the dosage, and 9,190 cGy (rad) to the stomach - 3.3% of the dosage.
  - Post-treatment Bremsstrahlung scan - microspheres in left lobe and stomach.
  - Prescribed prophylactic medication to help prevent ulceration.
  - Subsequent nausea and vomiting.

87

35.1000 Y-90 SirSphere® Events

Wrong site other lobe and stomach (cont.)

- Endoscopy 24 days later - mild to moderate erythema in the gastric antrum - expected to resolve in one to two weeks with continued treatment.
- Most likely cause:
  - Undetected movement of the catheter tip.
  - Possibly from patient movement.
  - Movement exacerbated by reduced slack in the catheter after pulling it back to correct its initial position.
- Corrective Actions: updating procedures and retraining personnel.

88

35.1000 Y-90 SirSphere® Events

Wrong site – spleen

- Prescribed to receive 779.22 MBq (21.06 mCi) to the liver, received 114.7 MBq (3.1 mCi) – 15% of dosage
- 259 MBq (7 mCi) [10,648 cGy (rad)] delivered to the patient's spleen.
  - Felt syringe pressure - using smaller gauge syringe made no difference – stopped treatment.
  - Microspheres clumping in the catheter and obstructing flow.
  - Suspected during catheter withdrawal the microspheres flowed into the larger splenic artery.
- Three days later reported observed uptake in spleen.

89

35.1000 Y-90 SirSphere® Events

Wrong site – spleen (cont.)

- Results of investigation - no physical obstruction, catheter placement was correct, no errors in the administration, no other causes identified.
- Patient monitored for any adverse impacts developed.
- Possible ways to prevent recurrence were identified and detailed in licensee's report. Corrective actions included generating a new written procedure.

90

35.1000 Y-90 SirSphere® Events

Wrong site – work around

- Patient scheduled for treatment to segments 7 and 8 of the right lobe of the liver, followed by second administration to segments 5 and 6 of the right lobe.
- Written directive - first treatment to left lobe, but already surgically removed.
  - Manufacturer's calculation sheet did not allow two treatments to the same lobe.
  - Authorized user put one treatment in each lobe to get activity for each part of the right lobe.
  - Not corrected when going from planned treatment to written directive.

91

35.1000 Y-90 SirSphere® Events

Wrong site - work around (cont.)

- Radiation Safety Office prepares the written directive for signature of the authorized user.
- Authorized user failed to correct the written directive error but realized after first treatment.
- Intended for the right lobe and administered correct dosage to the right lobe.
- Discovered 22 days later.

92

35.1000 Y-90 SirSphere® Events

Wrong site - work around (cont.)

- Corrective Actions:
  - Revised written directive preparation procedures.
  - Added another time-out for treatment details.
  - Trained all authorized users on modifications.
  - The authorized user not Radiation Safety Office to complete the written directive.
- Radiation Safety personnel present before procedure start to verify the correct patient is treated, the proper dose is administered, and the proper site is treated.

93

35.1000 Y-90 SirSphere® Events

Wrong lobe

- Prescribed 647.87 MBq (17.51 mCi) to the left lobe of the liver and 777 MBq (21 mCi) to the right lobe at a later date.
  - Facility typically treats right lobe before the left.
  - Failed to follow the written directive and recognize for this case, the left lobe was to be treated first.
  - Dosage administered to the right lobe was less than 20 percent of the planned later dosage.
  - The interventional radiologist discovered the error shortly after the procedure but did not think it had to be reported.

94

35.1000 Y-90 SirSphere® Events

Wrong lobe (cont.)

- Event discovered during routine inspection.
  - The written directive was not followed.
  - Dosage was delivered to an unintended site, this event should have been reported.
- Corrective Actions:
  - Revised policy and procedures.
  - Will prominently note the treatment lobe and stating the Y-90 procedure in the interventional radiology schedule and procedure board.
  - Time-out prior to the procedure start will include stating the laterality of the lobe.

95

35.1000 Y-90 SirSphere® Events

Licensee 1, Issue 1 - Aliquot

- Prescribed 429.2 MBq (11.6 mCi), received 316.72 MBq (8.56 mCi) - 74% of dosage.
- Dosage of 425.5 MBq (11.5 mCi) was small portion of the 7.13 GBq (192.6 mCi) in the unit vial.
- Microspheres remained in the administration system.

96

35.1000 Y-90 SirSphere® Events

Licensee 1, Issue 1 – Aliquot (cont.)

- Corrective Actions:
  - Order a dosage calibrated to give an activity closer to that needed for the date and time of administration.
  - Draw 10% greater than prescribed dosage for low administration activity.
  - Flushed system more in hopes of pushing more of the residual activity into the patient.

97

35.1000 Y-90 SirSphere® Events

Licensee 1, Issue 2 - Equipment

- Prescribed 1.2 GBq (32.43 mCi), received 0.46 GBq (12.43 mCi) – 38 % of dosage and less than 20% of dose.
- Interventional radiologist reported resistance in the line, with microspheres appearing to come out the top of the vial.
- Consulted with onsite manufacturer's representative.

98

35.1000 Y-90 SirSphere® Events

Licensee 1, Issue 2 – Equipment (cont.)

- The vial and administration kit sent to manufacturer for analysis.
  - Cause was failure of the administration equipment setup.
- Corrective Actions:
  - Use an updated administration set up for all future administrations.
  - Completed the patient administration - new written directive and new administration kit.

99

35.1000 Y-90 SirSphere® Events

Licensee 2, Issue 1 – Catheter backflow

- Two administrations – no issues with first – backflow into administration vial seen in second.
- Prescribed 453.99 MBq (12.27 mCi) to the right lobe in second administration, received 28% of the dosage.

100

35.1000 Y-90 SirSphere® Events

Licensee 2, Issue 2 – Catheter clogged

- Prescribed 1,100 cGy (rad) to segments 5 and 8 of the liver, received 250 cGy (rad) - 23%.
- 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

Catheter – Clogged/tip

- Received 31,500 cGy (rad) - 65% of dose
  - Issues with the delivery catheter during the procedure - catheter clogged, removed, and replaced during the procedure.
  - Thought Direxion HI-FLO microcatheter and angled tip was root cause of the clog.
- Manufacturer indicated all types of catheters can clog in normal use - plan other following up.
- Authorized user will use a microcatheter without the angled tip to avoid a similar event.

102

35.1000 Y-90 SirSphere® Events

Catheter - Occluded

- Prescribed 1.5 GBq (40.541 mCi), received 0.07 GBq (1.892 mCi) - 4.7% of dosage.
- The catheter could not be flushed - procedure stopped.
- First time using Embolx Sniper Microcatheter lot #EMB112818-05.
  - Uses a balloon to prevent potential backflow of the dose.
  - Smaller lumen than the catheters routinely used for this purpose.
- Catheter model will not be used for future treatments.

103*

35.1000 Y-90 SirSphere® Events

Patient movement dislodged IV

- Prescribed to receive 579.42 MBq (15.66 mCi), received 358.16 MBq (9.68 mCi).
- It was stated that the patient moved during the procedure and dislodged the IV.
- Licensee concluded no corrective actions needed to prevent recurrence.
  - Incident did not result in permanent functional damage to an organ.
  - Unavoidable due to patient movement.

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35.1000 Y-90 SirSphere® Events

Prescribed dosage, received 68% of the drawn activity.

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Acronyms

- µCi – microcurie
- AMP – authorized medical physicist
- AU – Authorized User
- cGy – centiGray
- CT – computed tomography
- FY – Fiscal Year
- GBq – Giga Becquerel
- HDR – High Dose Rate Remote Afterloader
- I-124 – Iodine-124
- I-131 – Iodine-131
- IVB – Intravascular Brachytherapy

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Acronyms

- Lu-177 – Lutetium-177
- MBq – Mega Becquerel
- mCi – millicurie
- MIBG - Metaiodobenzylguanidine
- Pd-103 – Palladium-103
- PET – positron emission tomography
- Ra-223 – Radium-223
- RSO – radiation safety officer
- SI units – International System of Units
- Sm-153 – Samarium-153
- Y-90 – Yttrium-90

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QUESTIONS?

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