Advisory Committee on the Medical Uses of Isotopes

Teleconference Meeting

May 27, 2021

Advisory Committee on the Medical Uses of Isotopes
TELECONFERENCE AGENDA
Thursday, May 27, 2021
1:00 PM – 5:00 PM EDT

OPEN SESSION		
	1. Opening Remarks Mr. Chris Einberg will formally open the meeting.	**C. Einberg, NRC**
1:00 PM – 5:00PM	**2. Medical Related Events** Dr. Said Daibes will provide an overview of the NRC staff's assessment of FY20 medical events.	**S. Daibes, PhD, NRC**
	3. Revised Abnormal Occurrence Criteria Mr. Mike Sheetz will discuss the ACMUI Abnormal Occurrence Subcommittee's draft report to include their review and comments on the NRC staff's proposed limited revisions to the abnormal occurrence criteria for medical events.	**M. Sheetz, ACMUI**

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

Status of Medical Events FY 2020

Said Daibes Figueroa, Ph.D.
Medical Radiation Safety Team
May 27, 2021

1

Medical Events

The dose threshold for diagnostic events precludes reportable events most years.

Each year, there are approximately 150,000 therapeutic procedures performed utilizing radioactive materials.

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Medical Events FY 2015 - 2017

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

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

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

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Medical Events FY 2018 - 2020

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

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

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Medical Events 2020

35.200 Medical events **0**

5

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Medical Events 2020

35.300 Medical events **2**

Lutetium-177 2

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35.300 Lu-177 Lutathera

Item Number: 200062

Lu-177 Lutathera **1**

Failure to start amino acid infusion

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

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

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Failure to start amino acid infusion (cont.)

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

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35.300 Leaking Foley Catheter

Item Number: 190569

Lu-177 Lutathera **2**

Leaking Foley Catheter

Patient received a skin injury.

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

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Medical Events 2020

35.400 Medical events 6

Prostate 4

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

Eye Plaque 2

– Overdose 1

– Under dose 1

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35.400 Medical Events

Item Number: 200056

Prostate: Wrong Site 1

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

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35.400 Wrong Site (cont.)

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

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35.400 Wrong Site (cont.)

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

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

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35.400 Wrong Site

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

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

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35.400 Wrong Site (cont.)

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

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

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35.400 Wrong Source

Item Number: 190525
Prostate: Wrong Source 1

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

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

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35.400 Wrong Source (cont.)

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

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35.400 Wrong Total Activity

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

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

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

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35.400 Wrong Total Activity (cont.)

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

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

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35.400 Wrong Dose

Item Number: 200249
Eye Plaque: Overdose 1

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

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35.400 Wrong Dose

Item Number: 190558
Eye Plaque: Under Dose 1

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

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35.400 Wrong Dose (cont.)

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

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Medical Events 2020

35.600 Medical events **13**

HDR

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

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Medical Events 2020 (cont.)

35.600 Medical events **13**

HDR

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

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35.600 HDR Events

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

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

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

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

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35.600 HDR Events

Item Number: 200135

Catheter- displaced cylinder 2

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

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Catheter-Displaced Cylinder (cont.)

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

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35.600 Wrong Site

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

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

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Applicator Inserted Rectal Cavity (cont.)

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

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

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Applicator Inserted Rectal Cavity (cont.)

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

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35.600 HDR Events

Item Number: 200258

Wrong site- Applicator inserted rectal cavity 4

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

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Applicator Inserted Rectal Cavity (cont.)

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

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

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35.600 HDR Events

Item Number: 200233
Wrong site- Wrong area treated 5

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

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Wrong site- Wrong area treated (cont.)

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

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35.600 HDR Events

Item Number: 200378
Catheter- wrong catheter 1

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

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Catheter- wrong catheter (cont.)

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

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35.600 HDR Events

Item Number: 200275
Catheter- Wrong data catheter entry 2

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

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Catheter- Wrong data catheter entry (cont.)

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

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35.600 HDR Events

Item Number: 200257

Broken tandem 1

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

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Broken Tandem (cont.)

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

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35.600 HDR Events

Item Number: 200001

Dislodged Applicator 1

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

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Dislodged Applicator (cont.)

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

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35.600 HDR Events

Item Number: 200206
Wrong plan-digitization error 1

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

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Wrong plan-digitization error (cont.)

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

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Wrong plan-digitization error (cont.)

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

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35.600 HDR Events

Item Number: 200083

Hand skin lesion- digitization error 1

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

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Hand Skin Lesion-Digitization Error (cont.)

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

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35.600 HDR Events

Item Number: 190571

Neck lesion 1

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

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

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Neck Lesion (cont.)

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

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Neck Lesion (cont.)

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

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35.600 HDR Events

Item Number: 200214

Breast lesion- Device Malfunction 1

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

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Breast lesion- Device Malfunction (cont.)

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

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Breast lesion- Device Malfunction (cont.)

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

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Medical Events 2020

35.1000 Medical events **27**

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

Y-90 Microspheres **23**

- Therasphere® 15
- SirSphere® 8

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35.1000 Perfexion

Item Number: 200136

Perfexion - Head frame slipped **1**

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

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Perfexion - Head frame slipped (cont.)

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

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35.1000 Perfexion

Item Number: 190538

Perfexion-Equipment Failure 2

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

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Perfexion-Equipment Failure (cont.)

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

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35.1000 Intravascular Brachytherapy

Item Number: 200189

Wrong site 1

Patient received dose to two unintended locations.

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

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Wrong site (cont.)

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

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Wrong site (cont.)

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

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35.1000 Radioactive Breast Seed Localization

Item Number: 190572
Breast: Seed Migration 1

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

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Breast: Seed Migration (cont.)

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

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35.1000 Medical Events

Y-90 Microspheres **23**

Therasphere ® **15**

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

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35.1000 Y-90 Therasphere® Events

Item Number: 200304

Procedure not followed **1**

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

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

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35.1000 Y-90 Therasphere® Events (cont.)

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

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35.1000 Y-90 Therasphere® Events

Item Number: 200279
Device connection leak 1

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

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

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35.1000 Y-90 Therasphere® Events (cont.)

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

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35.1000 Y-90 Therasphere® Events

Item Number: 190612
Spill **1**

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

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

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35.1000 Y-90 Therasphere® Events (cont.)

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

71

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35.1000 Y-90 Therasphere® Events

Item Number: 200363
Catheter issues- catheter slipped 1

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

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

72

72

35.1000 Y-90 Therasphere® Events (cont.)

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

73

73

35.1000 Y-90 Therasphere® Events

Item Number: 200005
Catheter-wrong tubing 2

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

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

74

74

35.1000 Y-90 Therasphere® Events (cont.)

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

75

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35.1000 Y-90 Therasphere® Events

Item Number: 190505
Catheter-extension tube issue 3

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

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

76

76

35.1000 Y-90 Therasphere® Events (cont.)

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

77

77

35.1000 Y-90 Therasphere® Events (cont.)

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

78

78

35.1000 Y-90 Therasphere® Events

Item Number: 200212
Catheter-kink microcatheter 4

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

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

79

79

35.1000 Y-90 Therasphere® Events (cont.)

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

80

80

35.1000 Y-90 Therasphere® Events (cont.)

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

81

81

35.1000 Y-90 Therasphere® Events

Item Number: 200320
Wrong lobe 1

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

82

82

35.1000 Y-90 Therasphere® Events (cont.)

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

83

83

35.1000 Y-90 Therasphere® Events

Item Number: 200169
Tubing occlusion 1

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

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

84

84

35.1000 Y-90 Therasphere® Events (cont.)

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

85

85

35.1000 Y-90 Therasphere® Events

Item Number: 200071
Tubing occlusion 2

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

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

86

86

35.1000 Y-90 Therasphere® Events (cont.)

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

87

87

35.1000 Y-90 Therasphere® Events

Item Number: 200336
Tubing occlusion 3

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

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

88

88

35.1000 Y-90 Therasphere® Events (cont.)

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

89

89

35.1000 Y-90 Therasphere® Events

Item Number: 200286
Clumping in microcatheter 1

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

90

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35.1000 Y-90 Therasphere® Events (cont)

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

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91

35.1000 Y-90 Therasphere® Events

Item Number: 200314
Clumping **2**

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

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

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92

35.1000 Y-90 Therasphere® Events (cont.)

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

93

93

35.1000 Y-90 Therasphere® Events

Item Number: 200193
Equipment Failure 1

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

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

94

94

35.1000 Y-90 Therasphere® Events

Item Number: 200075
Unknown failure 1

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

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

95

95

35.1000 Y-90 Therasphere® Events (cont.)

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

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

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35.1000 Medical Events

SirSphere ® 8

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

97

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35.1000 Y-90 SirSphere® Events

Item Number: 200366
Vial leakage **1**

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

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

98

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35.1000 Y-90 SirSphere® Events (cont.)

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

99

99

35.1000 Y-90 SirSphere® Events

Item Number: 200190

Vial leakage 2

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

100

100

35.1000 Y-90 SirSphere® Events (cont.)

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

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35.1000 Y-90 SirSphere® Events (cont.)

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

102

102

35.1000 Y-90 SirSphere® Events

Item Number: 190597
Equipment – ruptured line 1

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

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35.1000 Y-90 SirSphere® Events (cont.)

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

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35.1000 Y-90 SirSphere® Events (cont.)

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

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35.1000 Y-90 SirSphere® Events

Item Number: 200373

Catheter – Clogged/tip 1

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

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35.1000 Y-90 SirSphere® Events

Item Number: 200330

Catheter – Clogged 2

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

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35.1000 Y-90 SirSphere® Events

Item Number: 200155

Catheter – Activity remained in tubing, vial and catheter 3

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

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35.1000 Y-90 SirSphere® Events

Item Number: 190602

Catheter – Residual activity in tubing 4

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

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35.1000 Y-90 SirSphere® Events

Item Number: 190577

Catheter- occluded 5

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

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35.1000 Y-90 SirSphere® Events (cont.)

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

111

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35.1000 Y-90 SirSphere® Events (cont.)

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

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Acronyms

- µCi – microcurie
- AMP – authorized medical physicist
- AU – Authorized User
- Cs-131 – Cesium-131
- cGy – centiGray
- CT – computed tomography
- FY – Fiscal Year
- GBq – Giga Becquerel
- Gy – Gray
- HDR – High-Dose Rate Remote Afterloader

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Acronyms

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

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QUESTIONS?

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Abnormal Occurrence Subcommittee Draft Report

Michael Sheetz

Advisory Committee on the Medical Use of Isotopes

May 27, 2021

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Subcommittee Members

- Ronald Ennis, MD
- Hossein Jadvar, MD, PhD
- Zoubir Ouhib
- Michael Sheetz (Chair)
- Megan Shober

- NRC Staff Resource: Donna-Beth Howe, PhD

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Subcommittee Charge

- Define patient harm in medical AO
- Reassess the current medical AO criteria
- Define goals of AO criteria and reporting
- Evaluate whether the current medical AO criteria are appropriate regarding public health and safety

3

Abnormal Occurrence Criteria

- Inform Congress and public of unscheduled incidents or events which NRC considers significant from the standpoint of public health and safety
- NRC Annual AO Report (NUREG-0090)
  - Date and place of each occurrence
  - Nature and probable consequence
  - Cause or causes
  - Action taken to prevent reoccurrence

4

Current Medical AO Criteria (2017)

- Medical Event must meet both a dose threshold and incident criteria
- Dose Threshold
  - Equal or greater than
    - 1 Gy to bone marrow or lens of the eye
    - 2.5 Gy to the gonads, or
  - Exceeds, by 10 Gy, the expected dose to any other tissue

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Current Medical AO Criteria (2017)

- Incident Criteria
  - Dose that is at least 50% greater than prescribed
  - Wrong radiopharmaceutical, route of administration, or treatment mode
  - Leaking source
  - Wrong patient or research subject

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2013 ACMUI Recommendation

- Medical Event that results in one of the following:
  - —Unintended or unexpected permanent functional damage to an organ
  - —Unintended or unexpected permanent functional damage to a physiological system
  - —A significant unexpected adverse health effect
  - —Death
- Notification of event involving unintended dose to embryo/fetus that results in a significant adverse health impact

Evaluation of Current Medical AO Criteria

- NRC concludes that medical event AO criteria may capture events that are not significant from the standpoint of public health or safety
- ACMUI concurs that current medical event AO criteria are not appropriate and need to be reviewed and revised
- Commission approves the NRC recommendation to develop and propose a limited revision to the AO criteria in the medical event area

NRC Proposed Changes to Medical Event AO Criteria

- Adds medical event definitions for uses regulated under 10 CFR 35.1000
- Retains current dose threshold criteria and addresses dose from prescribed dosage or activity
- Eliminates requirement for a written directive
- Addition of a medical-consequence criterion to the dose-based AO criteria
  - Unintended radiation induced injury causing permanent impairment of bodily function or permanent damage to a body structure
  - Or surgical intervention is needed to preclude permanent impairment

Evaluation of Proposed Changes

- Current medical AO criteria are too conservative
- Goal of AO reporting is to elevate significant events to the level of Congressional and Public attention
- NRC proposed changes establish a two-step criterion for medical events to be reported as an AO
- NRC has responsibility to determine whether both the dose and radiation induced injury criteria are met, and when medical events are determined to be AOs

Analysis of Number of Medical AOs Reported by Criteria

- Average of 12 medical AOs reported to Congress each year (2010-2020)
- No significant difference in number reported based on pre- or post-2017 criteria
- Proposed AO criteria would reduce number to 3 or 4 medical AOs reported to Congress each year
- New medical AO criteria will better identify those events that are significant from a public health or safety perspective, and eliminate reporting of events with little or no adverse health consequence

AO Subcommittee Recommendations

- Subcommittee fully supports the NRC proposed changes to the Medical AO criteria
- Subcommittee recommends that communication be prepared for distribution to all NRC and Agreement State medical licensees to inform of best practices in preparing a medical event report so that complete and accurate information is provided in describing the event, root cause analysis on why the event occurred, and the medical effect on the individual

AO Subcommittee Member Dissenting Opinion (M. Sheetz)

- Disagrees on embryo/fetal events reported under 10 CFR 35.3047 being included in AO criteria I.A.2. with a dose threshold of 50 mSv
- Supports previous AO subcommittees' position that medical-related events reported under 35.3047 be screened under same AO criteria for medical use of radioactive material
- Supports events reported under 35.3047 be included under AO criteria III.C. which will result in unintended radiation induced injury causing permanent impairment or damage

Acronyms

- ACMUI – Advisory Committee on the Medical Use of Isotopes
- AO – Abnormal Occurrence
- Gy – Gray
- mSv – millisievert
- NRC – Nuclear Regulatory Commission

U.S. Nuclear Regulatory Commission
Advisory Committee on the Medical Use of Isotopes

Abnormal Occurrence Subcommittee

Draft Report

May 12, 2021

Subcommittee Members:
Dr. Ronald Ennis
Dr. Hossein Jadvar
Mr. Zoubir Ouhib
Mr. Michael Sheetz (Chair)
Ms. Megan Shober
NRC Staff Resource: Dr. Donna-Beth Howe

Subcommittee Charge:
During the March 30, 2020 Advisory Committee on the Medical Uses of Isotopes (ACMUI) Meeting, ACMUI Chairman, Dr. Darlene Metter, established an Abnormal Occurrence (AO) Subcommittee to (1) Define patient harm in AO; (2) Reassess the current AO criteria; (3) Define goals of AO criteria and reporting; (4) Evaluate whether the current AO criteria are appropriate regarding public health and safety: and (5) Comment on any NRC staff proposed AO changes. This subcommittee was delayed until July 27, 2020, following approval by the Commission for U.S. Nuclear Regulatory Commission (NRC) staff to develop and propose a limited revision to the AO criteria in the medical event area.

Background:
The NRC policy statement on AO criteria was developed to comply with Section 208 of the Energy Reorganization Act of 1974, as amended, and initially published in the Federal Register on February 24, 1977 (42 FR 10950)[1]. The intent of the act is to keep Congress and the public informed of unscheduled incidents or events which the NRC considers significant from the standpoint of public health and safety. The policy reflects a range of health and safety concerns and applies to incidents and events involving a single individual, as well as those having overall impact on the general public. An AO is defined as "an unscheduled incident or event which the NRC determines to be significant from the standpoint of public health or safety".

AOs are required to be reported annually to Congress, and that the discussion of each event must include (1) the date and place of each occurrence; (2) the nature and probable consequence of each occurrence; (3) the cause or causes of each; and (4) any action taken to prevent reoccurrence. The AO report is also widely disseminated to the public within 15 days of sending it to Congress.

The AO criteria has been revised several times, with the most recent revision to the medical AO criteria being published in the Federal Register on October 2, 2017 (82 FR 45907)[2].

In leading up to this revision, the NRC prepared its March 15, 2015 SECY-15-0040[3] paper to inform the Commission that it was proposing revisions to the AO criteria. The ACMUI provided comments on the draft SECY Paper in its AO subcommittee report dated April 15, 2013[4]. The ACMUI recommended removing the applicability of AO criteria from section I.A.2. for

notifications of embryo/fetal exposures reported under 10 CFR 35.3047, and replacing the dose criteria in Section III.C. to:

1. Medical Event that, as determined by a consultant physician(s) deemed qualified by NRC or an Agreement State, results in one or more of the following:

    a. Unintended or unexpected permanent functional damage to an organ.
    b. Unintended or unexpected permanent functional damage to a physiological system.
    c. A significant unexpected adverse health effect.
    d. Death.

2. Notification under 10 CFR 35.3047 of an event involving an unintended dose to an embryo/fetus or a nursing child that results in a significant adverse health impact to the embryo/fetus or child, as determined by a consultant physician(s) deemed qualified by NRC or an Agreement State.

The NRC did not agree with the movement of the AO criteria for embryo/fetal exposures reported under 10 CFR 35.3047 to section III.C. However, the NRC kept the Medical Event and dose criteria in section III.C. and included the ACMUI recommendation for unintended or unexpected permanent functional damage to an organ or a physiological system; a significant unexpected adverse health effect; or death.

The Commission's June 30, 2015 SRM-15-0040[5] approved publication of the draft revised AO criteria, however, the Commission removed the staff's (and ACMUI's) recommended text associated with unintended or unexpected permanent functional damage to an organ or a physiological system; a significant unexpected adverse health effect; or death.

The NRC published its proposed AO criteria for public comment in the Federal Register (30 FR 49177)[6] August 17, 2015. The ACMUI provided comments in its AO subcommittee final report dated November 6, 2015[7]. This document recommended once more to move the reporting of AOs for embryo/fetus notifications reported under 10 CFR 35.3047 to section III.C. and to make it the same as the AO criteria for a Medical Event, and once more recommended no dose criteria in section III.C. for medical event AO's but replacing it with a criterion of unintended permanent functional damage to an organ or a physiological system as determined by an independent physician deemed qualified by NRC or an Agreement State. The NRC published the revised AO criteria on October 2, 2017 (82 FR 45907).

In response to a Staff Requirements Memorandum (SRM-M190423)[8], the NRC conducted an evaluation of the AO criteria established in 2017 to determine whether the current AO criteria provide an appropriate threshold for determining if an incident or event is significant from the standpoint of public health and safety or whether the criteria should be revised (SECY-19-0088)[9]. This evaluation included a review of significant health effects associated with medical AOs over the past 5 years and included the results from previous evaluations from SECY-15-0040 and solicited input from the Organization of Agreement States and the ACMUI. The NRC concluded that the medical event AO criteria may capture events that are not significant from the standpoint of public health or safety and recommended that a limited revision to the medical event AO criteria be developed. In a July 24, 2019 Teleconference Meeting[10], the ACMUI concurred with the NRC staff's conclusion stating, "The current medical event abnormal occurrence criteria are not appropriate and need to be reviewed and revised." The Commission

approved the NRC recommendation to develop and propose a limited revision to the AO criteria in the medical event area on July 27, 2020[11].

NRC Proposed Revisions to Medical Event Abnormal Occurrence Criteria:

The following shows the current proposed changes from Enclosure 1 to the Medical Event AO criteria under Section III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events:

C. Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects[16]

1. A medical event, as defined in § 35.3045 or in a specific license (based on specific 10 CFR 35.1000 licensing guidance), which results in an unintended dose that:

   (a) Is equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal to or greater than 2.5 Gy (250 rad) to the gonads; or

   (b) Exceeds, by 10 Gy (1,000 rad), the ~~expected~~ dose or dose that would have resulted from delivery of the prescribed dose, prescribed dosage or prescribed activity to any other organ or tissue from the administration ~~defined in the written directive~~; and

2. A medical event, as defined in § 35.3045 or in a specific license (based on specific 10 CFR 35.1000 licensing guidance), ~~which involves~~that results or has high probability of resulting in:

   (a) ~~A dose or dosage that is at least 50 percent greater than that prescribed~~Radiation induced injury causing permanent impairment of bodily function or permanent damage to a body structure[17], or

   (b) Radiation induced injury in which medical or surgical intervention is needed to preclude permanent impairment of a bodily function or permanent damage to a body structure[17].

   ~~A prescribed dose or dosage that:~~

   ~~(i) Uses the wrong radiopharmaceutical or unsealed byproduct material; or~~

   ~~(ii) Is delivered by the wrong route of administration; or~~

   ~~(iii) Is delivered to the wrong treatment site; or~~

   ~~(iv) Is delivered by the wrong treatment mode; or~~

   ~~(v) Is from a leaking source or sources; or~~

   ~~(vi) Is delivered to the wrong individual or human research subject.~~

17 NRC will use dose and medical consequence information from the licensee, inspections, physicians (referring, licensee, or consultant physicians), other professionals (e.g., medical physicist, radiation biologist), and other resources to make its AO determination.

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Enclosure 2 provides a summary and explanation for each of the proposed changes to the Medical Event AO criteria.

Enclosure 3 provides a table showing the number of medical Abnormal Occurrence (AO) events reported to Congress by Fiscal Year (FY) from 2010 through 2020. It also includes the number of medical events reported to the NRC per FY, number that resulted in pre-2018 AO criteria, number under the revised 2018 criteria, and the number that had a high possibility of meeting the proposed medical-consequence AO criteria.

Discussion:

The ACMUI has repeatedly discussed concerns with NRC Staff that medical use incidents and events being included in AO reports may not be significant from the standpoint of public health or safety. The ACMUI has been concerned that the medical AO criteria is overly conservative and tends to capture medical events that are known risks for the procedure, and not significant from the standpoint of public health or safety. The ACMUI has also expressed concerns that the conservative nature of the current medical AO criteria has resulted in an over-representation of medical events in the AO report to Congress, which has led to the perception that medical use licensees have more significant radiation safety incidents than non-medical users of radioactive material. Since previous revision of the AO criteria, over 95% of the AOs reported to Congress are medical use related from which the majority did not expect any adverse health effects to the patient. AOs should have a reporting threshold such that only those events considered significant from the standpoint of public health or safety are reported to Congress. As previously stated, and endorsed by the ACMUI, a medical event AO should result in patient harm such as unintended or unexpected permanent functional damage to an organ or physiological system, a significant unexpected adverse health effect, or death.[9]

The subcommittee believes that the goal of AO reporting is to elevate significant events to the level of Congressional and Public attention so that they gain the appropriate consideration and resources for mitigation and corrective action necessary to prevent future similar occurrences. Reporting of events that are not significant with respect to public health or safety is inconsistent with the statutory threshold for what constitutes an AO and inappropriately introduces confusion as to the significance of the event. It is important to note that revising the medical AO reporting criteria will not adversely influence public health and safety. Regulatory reporting requirements of medical events currently applicable to NRC and Agreement State licensees remain in place. Therefore, licensees will continue to submit required reports on a broader range of medical events, and NRC and Agreement States will continue to monitor these events, identify trends, and evaluate performance and corrective actions.

The current NRC proposed changes establish a two-step criterion for Medical Events to be reported as an AO. The first would be to exceed some level of a tissue/organ dose threshold, and the second would be to result in some type of radiation induced patient injury. Both conditions must be met to be considered an AO. This would address the concerns from the regulatory community to have a discrete dose metric to eliminate potential AOs below this threshold, and the concerns from the ACMUI (and others) to have some measurement of significant patient harm that decides if the event is an AO. The dose threshold levels are essentially the same as in the current AO criteria, with the addition of the condition that it is an unexpected dose in excess of that intended from the prescribed dose, dosage, or activity. The radiation induced injury criteria are deterministic effects that either result or have a high probability of resulting in permanent impairment of bodily function or permanent damage to a

body structure, or in which medical or surgical intervention is needed to preclude permanent impairment of a bodily function or permanent damage to a body structure.

The NRC has the responsibility to determine whether both the dose and radiation induced injury criteria are met, and when medical events are determined to be AOs. The NRC will make this determination based on dose and medical consequence information provided by the licensee, inspections, physicians (referring, licensee, or independent physicians), other health care professionals (including medical physicist and radiation biologists), and other resources. While the current Medical Event reporting requires a brief description of the event; why the event occurred; the effect, if any, on the individual(s) who received the administration; and what actions, if any, have been taken or are planned to prevent recurrence; it will be especially important for licensees to provide complete and accurate information to allow the NRC to make an appropriate AO determination.

From the data in Enclosure 3, "Retrospective Review of the Medical Events reported to NRC between 2010 and 2020 and to Congress as AOs", there have been an average of 12 medical AOs reported to Congress each year. The table shows that there was essentially no difference in determining the medical events reported as AOs before 2017 and determining if they were AOs based on the 2018 criteria. However, the newly proposed AO criteria would reduce this number to an average of 3 or 4 medical AOs reported to Congress each year. Based on this review, the newly proposed medical AO criteria will better identify those medical events that are significant from a public health or safety perspective and eliminate reporting of those medical events with little or no adverse health consequence.

Subcommittee Recommendations:

1. The Subcommittee fully supports the proposed changes to the medical AO criteria as outlined in Enclosure 1.

2. The Subcommittee recommends that some type of communication be prepared for distribution to all NRC and Agreement State medical licensees to inform them of best practices in preparing a medical event report so that complete and accurate information is provided in describing the event, root cause analysis on why the event occurred, and the medical effect on the individual(s). This same recommendation was also previously made by the ACMUI Subcommittee on the Appropriateness of Medical Event Reporting[12].

References:

1. Federal Register, 10950, February 24, 1977, Vol. 42, No. 37, Nuclear Regulatory Commission, Policy Statement on Abnormal Occurrence Criteria
2. Federal Register, 45907, October 2, 2017, Vol. 82, No. 189, Nuclear Regulatory Commission, Revised Policy Statement on Abnormal Occurrence Criteria
3. NRC SECY-15-0040, Proposed Revisions to Policy Statement on Reporting Abnormal Occurrence Criteria, March 19, 2015
4. ACMUI, Report on Abnormal Occurrence Criteria for Medical Use, April 15, 2013
5. NRC SRM-15-0040, Proposed Revisions to Policy Statement on Reporting Abnormal Occurrence Criteria, June 30, 2015

6. Federal Register, 49177, August 17, 2015, Vol. 80, No. 158, Nuclear Regulatory Commission, Abnormal Occurrence Reports – Proposed Revision to Policy Statement; Request for Comments
7. ACMUI, Final Comments on Proposed Revision of the NRC Policy Statement on Reporting Abnormal Occurrences to Congress, November 6, 2015
8. NRC SRM-M190423, Briefing on Strategic Programmatic Overview of the Fuel Facilities and the Nuclear Materials Users Business Lines, May 8, 2019
9. NRC SECY-19-0088 Evaluation of Thresholds for Reporting Abnormal Occurrences in Response to SRM-M190423, September 16, 2019
10. ACMUI Teleconference, Meeting Summary, July 24, 2019
11. NRC SRM-19-0088, Staff Requirements - SECY-19-0088 - Evaluation of Thresholds for Reporting Abnormal Occurrences in Response to SRM-M190423, July 27, 2020
12. ACMUI Subcommittee on the Appropriateness of Medical Event Reporting, Draft Report, August 28, 2019

Respectfully submitted, May 12, 2021
Abnormal Occurrence Subcommittee
Advisory Committee on the Medical Use of Isotopes
U.S. Nuclear Regulatory Commission

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Dissenting Opinion:

One member of the current AO subcommittee has a different perspective on reports of embryo/fetal events reported under 10 CFR 35.3047 being included in AO criterion I.A.2. with a dose threshold of 50 mSv. While this criterion was not part of the current NRC proposed changes, it was previously addressed in the two prior ACMUI AO subcommittee reports. This subcommittee member supports the previous AO subcommittees' position that medical-related events reported under 35.3047 be screened under AO Criteria III.C. since the event exposure was due to the medical use of radioactive material. It is inappropriate to judge any medical related exposures under AO criterion I.A. (Human Exposure to Radiation from Licensed Material) due to the relatively low dose threshold criterion. It is also inconsistent with the goal of the AO criteria and the current NRC proposed revisions to have a threshold level set that is not significant with respect to health or safety. The AO criteria should be a high reporting threshold so that only those events considered significant from the standpoint of public health or safety and result in measurable harm are reported to Congress. Embryo/fetal exposures of 50 mSv would not result in any deterministic effects and have an exceedingly small potential increased risk for stochastic effects. The current low dose threshold criterion for an unintended dose to an embryo/fetus will continue to result in several reported AOs each year from radiopharmaceutical therapy patients unknowingly being pregnant at the time of their therapy. The argument that there should not be two different thresholds for reporting an AO involving exposure to an embryo/fetus; one for an embryo/fetus unintentionally exposed due to a medical administration to a pregnant individual and one for an embryo/fetus exposed from all other sources of licensed material, ignores that there are already two different regulatory reporting thresholds for the embryo/fetus, one in 35.3047 for medical use and the other in 20.2203(a)(2)(iv) for general radiation protection. This subcommittee member supports excluding events reported under 35.3047 from the AO criteria in I.A.2. and including these events under AO criteria in III.C. which will result in unintended radiation induced injury causing permanent impairment of bodily function or permanent damage to a body structure.

Respectfully submitted,
Michael Sheetz

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APPENDIX A
ABNORMAL OCCURRENCE CRITERIA

ABNORMAL OCCURRENCE GENERAL STATEMENT OF POLICY

The U.S. Nuclear Regulatory Commission (NRC) will apply the following policy in determining whether an incident or event at a facility or involving an activity that is licensed or otherwise regulated by the Commission or an Agreement State is an abnormal occurrence (AO):[1]

> An incident or event is considered an AO if it involves a major reduction in the protection of public health or safety. The incident or event has a moderate or severe impact on public health or safety and could include, but need not be limited to, the following:
>
> (1) Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission or Agreement State;
>
> (2) Major degradation of essential safety-related equipment;
>
> (3) Major deficiencies in design, construction, use of, or management controls for, facilities or radioactive material licensed by or otherwise regulated by the Commission or Agreement State; or
>
> (4) Substantiated case of actual loss, theft, or diversion of risk-significant radioactive material licensed by or otherwise regulated by the Commission or Agreement State.

The NRC identified the criteria below for determining an AO and the guidelines for "other events of interest" in a policy statement published in Volume 82 of the *Federal Register*, page 45907 (82 FR 45907; October 2, 2017).

Abnormal Occurrence Criteria

The following presents the criteria, by types of events, used to determine which events will be considered for reporting as AOs.

I. All Licensees[2]

A. Human Exposure to Radiation from Licensed Material

1. Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in:

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[1] Events reported to the NRC by Agreement States that reach the threshold for reporting as AOs will be reported as such by the Commission.

[2] Medical patients and human research subjects are excluded from consideration under these criteria, and these criteria do not apply to medical events defined in § 35.3045 of Title 10 of the Code of *Federal Regulations* (10 CFR), "Report and notification of a medical event," which are considered in AO Criteria III.C.

(a) An annual total effective dose equivalent (TEDE) of 250 millisieverts (mSv) (25 rem) or more;

(b) An annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ other than the lens of the eye, the bone marrow, and the gonads of 2,500 mSv (250 rem) or more;

(c) An annual dose equivalent to the lens of the eye of 1 Sievert (Sv) (100 rem) or more;

(d) An annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow of 1 Sv (100 rem) or more;

(e) A committed dose equivalent to the gonads of 2,500 mSv (250 rem) or more; or

(f) An annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more.

2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.

3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by an independent physician[3] deemed qualified by the NRC or Agreement State.

B. Discharge or Dispersal of Radioactive Material from Its Intended Place of Confinement

The release of radioactive material to an unrestricted area in concentrations that, if averaged over a period of 24 hours, exceed 5,000 times the values specified in Table 2 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," to 10 CFR part 20, "Standards for protection against radiation," unless the licensee has demonstrated compliance with § 20.1301, "Dose limits for individual members of the public," using § 20.1302(b)(1) or § 20.1302(b)(2)(ii). This criterion does not apply to transportation events.

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[3] "Independent physician" is defined as a physician not on the licensee's staff and who was not involved in the care of the patient involved.

C. Theft, Diversion, or Loss of Licensed Material; Sabotage; or Security Breach[4,5,6]

1. Any stolen, diverted, abandoned, or unrecovered lost radioactive material that meets or exceeds the thresholds listed in Appendix A, "Category 1 and Category 2 Radioactive Materials," to 10 CFR part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Excluded from reporting under this criterion are the following types of events:

   (a) ~~t~~Those events involving sources that are lost or abandoned under the following conditions: sources that have been lost and for which a reasonable attempt at recovery has been made without success, or irretrievable well logging sources as defined in § 39.2, "Definitions." These sources are only excluded if there is reasonable assurance that the doses from these sources have not exceeded, and will not exceed, the reporting thresholds specified in AO Criteria I.A.1 and I.A.2 and the agency has determined that the risk of theft or diversion is acceptably low.

   ~~(a)~~(b) Those events involving sources that are stolen, diverted, or abandoned only if it is evident that there was no intent to gain access to the radioactive material and the sources were recovered with little or no risk to public health or safety.

2. An act that results in radiological sabotage as defined in §37.5 and § 73.2.

3. Any substantiated[7] case of actual theft, diversion, or loss of a formula quantity of special nuclear material,[8] or an inventory discrepancy of a

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4 Information pertaining to certain incidents may either be classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Executive Order 13526, "Classified National Security Information," as amended (75 FR 707; January 5, 2010), or any predecessor or successor order to require protection against unauthorized disclosures. Any classified details about these incidents would be available to Congress upon request, under appropriate security arrangements.

5 Information pertaining to certain incidents may be Safeguards Information as defined in § 73.2 because of safety and security implications. The AO report would withhold specific Safeguards Information in accordance with Section 147 of the Atomic Energy Act of 1954, as amended. Any safeguards details regarding these incidents would be available to Congress upon request, under appropriate security arrangements.

6 Reporting lost or stolen material is based on the activity of the source at the time the radioactive material was known to be lost or stolen. If, by the time the AO report is due to Congress, the radioactive material has decayed below the thresholds listed in Appendix A to 10 CFR part 37, the report will clarify that the radioactive material has decayed below the thresholds.

7 "Substantiated" means a situation in which there is an indication of loss, theft, or unlawful diversion, such as an allegation of diversion, report of lost or stolen material, or other indication of loss of material control or accountability that cannot be refuted following an investigation, and requires further action on the part of the agency or other proper authorities.

8 "Formula quantity of special nuclear material" is defined in § 70.4, "Definitions."

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formula quantity of special nuclear material that is judged to be caused by theft or diversion.

4. Any substantial breakdown[9] of physical security, cyber security, or material control and accountability programs that significantly weakens the protection against loss, theft, diversion, or sabotage.

5. Any significant unauthorized disclosures (loss, theft, and/or deliberate disclosure) of classified information that harms national security or of Safeguards Information that threatens public health or safety.

D. Initiation of High-Level NRC Team Inspection[10]

II. Commercial Nuclear Power Plant Licensees

A. Malfunction of Facility, Structures, or Equipment

1. Exceeding a safety limit of a license technical specification (TS) (§ § 50.36(c)).

2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials that could result in exceeding the dose limits of 10 CFR part 100, "Reactor site criteria," or five times the dose limits of General Design Criteria (GDC) 19, "Control Room," in Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR part 50, "Domestic licensing of production and utilization facilities," could occur from a postulated transient or accident (*e.g.,* loss of emergency core cooling system, loss of control rod system).

B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy

1. Discovery of a major condition not specifically considered in the safety analysis report or TS that requires immediate remedial action.

2. Personnel error or procedural deficiencies that result in the loss of plant capability to perform essential safety functions such that a release of radioactive materials exceeding the dose limits of 10 CFR part 100 or five times the dose limits of GDC 19 in Appendix A to 10 CFR part 50, could

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[9] A substantial breakdown is defined as a red finding under the Reactor Oversight Process (ROP) in the physical security inspection program or any plant or facility determined to have overall unacceptable performance.

[10] This item addresses the initiation of any incident investigation teams, as described in NRC Management Directive (MD) 8.3, "NRC Incident Investigation Program" (ADAMS Accession No. ML13175A294), or initiation of any accident review groups, as described in MD 8.9, "Accident Investigation" (ADAMS Accession No. ML13319A133).

occur from a postulated transient or accident (*e.g.,* loss of emergency core cooling system, loss of control rod drive mechanism).

C. Any operating reactor events or conditions evaluated by the NRC ROP to be the result of or associated with licensee performance issues of high safety significance.[11]

D. Any operating reactor events or conditions evaluated by the NRC Accident Sequence Precursor (ASP) program to have a conditional core damage probability (CCDP) or change in core damage probability (ΔCDP) of greater than or equal to 1×10^{-3}.[12]

E. Any operating reactor plants that are determined to have overall unacceptable performance or are in a shutdown condition as a result of significant performance problems and/or operational event(s).[13]

III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events

A. Events Involving Design, Analysis, Construction, Testing, Operation, Transport, Use, or Disposal

1. An accidental criticality.

2. A major deficiency in design, construction, control, or operation having significant safety implications that require immediate remedial action.

3. A serious safety-significant deficiency in management or procedural controls.

4. A series of events (in which the individual events are not of major importance), recurring incidents, or incidents with implications for similar facilities (generic incidents) that raise a major safety concern.

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[11] The NRC ROP uses four colors to describe the safety significance of licensee performance. As defined in NRC MD 8.13, "Reactor Oversight Process" (ADAMS Accession No. ML17347B670), green is used for very low safety significance, white is used for low to moderate safety significance, yellow is used for substantial safety significance, and red is used for high safety significance. Reactor conditions or performance indicators evaluated to be red are considered AOs.

[12] Results from the NRC Accident Sequence Precursor program are used to monitor agency performance against the agency's strategic safety goal (e.g., ensure the safe use of radioactive materials) and objectives (e.g., prevent and mitigate accidents and ensure radiation safety). A precursor event with a CCDP or ΔCDP of greater than or equal to 1×10^{-3} is used as a performance indicator for the strategic safety goal by determining that there have been no significant precursors of a nuclear reactor accident and that there have been no more than one significant adverse trend in industry safety performance.

[13] Any plants assessed by the ROP to be in the unacceptable performance column, as described in NRC Inspection Manual Chapter (IMC) 0305, "Operating Reactor Assessment Program" (ADAMS Accession No. ML19256A191), or under NRC IMC 0350, "Oversight of Reactor Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns" (ADAMS Accession No. ML17116A273). This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

B. Fuel Cycle Facilities[14]

1. Absence or failure of all safety controls (engineered and human) such that conditions were present for the occurrence of a high-consequence event involving an NRC-regulated hazard (radiological or chemical).[15]

2. An NRC-ordered safety-related or security-related immediate remedial action.

C. Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects[16]

1. A medical event, as defined in § 35.3045 or in a specific license (based on specific 10 CFR 35.1000 licensing guidance), which results in an unintended dose that:

   (a) Is equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal to or greater than 2.5 Gy (250 rad) to the gonads; or

   (b) Exceeds, by 10 Gy (1,000 rad), the ~~expected~~ dose or dose that would have resulted from delivery of the prescribed dose, prescribed dosage or prescribed activity to any other organ or tissue from the administration ~~defined in the written directive~~; and

2. A medical event, as defined in § 35.3045 or in a specific license (based on specific 10 CFR 35.1000 licensing guidance), ~~which involves~~that results or has high probability of resulting in:

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[14] Criterion III.A also applies to fuel cycle facilities.

[15] High-consequence events for facilities licensed under 10 CFR part 70, "Domestic licensing of special nuclear material," are those that could seriously harm the worker or a member of the public in accordance with § 70.61, "Performance requirements." The integrated safety analysis conducted and maintained by the licensee or applicant of 10 CFR part 70 fuel cycle facilities identifies such hazards and the safety controls (§ 70.62(c)) applied to meet the performance requirements in accordance with § 70.61(b) through (d).

Fuel cycle facilities licensed under 10 CFR part 40, "Domestic licensing of source material," or certified under 10 CFR part 76, "Certification of gaseous diffusion plants," have licensing basis documents that describe facility specific hazards, consequences, and those controls used to prevent or mitigate the consequences of such accidents. For these facilities, a high-consequence event would be a release that has the potential to cause acute radiological or chemical exposures to a worker or a member of the public similar to that defined in Appendix A to Chapter 3, Section A.2, of NUREG 1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications—Final Report," issued June 2015, under "Consequence Category 3 (High Consequences)" (ADAMS Accession No. ML15176A258).

[16] Criteria III.A.2, III.A.3, and III.A.4 also apply to medical licensees.

(a) ~~A dose or dosage that is at least 50 percent greater than that prescribed~~Radiation induced injury causing permanent impairment of bodily function or permanent damage to a body structure[17], or

(b) Radiation induced injury in which medical or surgical intervention is needed to preclude permanent impairment of a bodily function or permanent damage to a body structure[17].

~~A prescribed dose or dosage that:~~

~~(i) Uses the wrong radiopharmaceutical or unsealed byproduct material; or~~

~~(ii) Is delivered by the wrong route of administration; or~~

~~(iii) Is delivered to the wrong treatment site; or~~

~~(iv) Is delivered by the wrong treatment mode; or~~

~~(v) Is from a leaking source or sources; or~~

~~(vi) Is delivered to the wrong individual or human research subject.~~

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[17] NRC will use dose and medical consequence information from the licensee, inspections, physicians (referring, licensee, or consultant physicians), other professionals (e.g., medical physicist, radiation biologist), and other resources to make its AO determination.

Summary of Abnormal Occurrence Criteria Changes

Section I.C., "Theft, Diversion, or Loss of Licensed Material; Sabotage; or Security Breach"

The staff is considering changes to the source security criteria to ensure that the abnormal occurrences (AOs) reported to Congress better capture all and only those events that are significant to public health or safety. As discussed in SECY-19-0088, the criteria in Section I.C., "Theft, Diversion, or Loss of Licensed Material; Sabotage; or Security Breach," require the reporting of any stolen, diverted, abandoned, or unrecovered lost radioactive material that meets or exceeds the Category 1 and Category 2 thresholds listed in Appendix A to Title 10 of the *Code of Federal Regulations* (CFR) Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," even if the sources are promptly recovered, and there is reasonable assurance that there was and is no risk to public health or safety. Under the current security criteria, if a stolen radiography camera that exceeds the threshold for category 2 quantity of radioactive material is recovered, and there is reasonable assurance that there was no tampering with the radiography camera and there was no intent to gain access to the radioactive material, the event must nevertheless be reported as an AO. Events could also be reported as AOs under the current criteria if abandoned or diverted category 1 or category 2 sources are subsequently and promptly recovered with no radiation risk to the public. The staff believes that these types of events do not pose a significant impact to public health or safety and do not warrant notification to Congress. To capture events that are significant to public health or safety, the staff proposes changes to the source security criteria by revising the exclusion reporting of criterion I.C.1 so as to exclude those events involving sources that are stolen, diverted, or abandoned where it is evident that there was no intent to gain access to the radioactive material and the sources are recovered with little or no risk to public health or safety (Enclosure 1).

Historical data of source security events reported as AOs from FY 2010 through FY 2020 were reviewed to gain insights on the potential revision to this reporting criterion to Congress. From this retrospective review, only three AO events (FY 2011, 2018, and 2019 AO Reports), all involving radiography cameras, met the current source security criteria during this ten-year time period. After reviewing the reported events, the staff concluded that two of the three events (in FY 2011 and 2019) would be reported as AOs under the proposed revised criteria. In the FY 2011 AO event, a radiography camera along with associated equipment was stolen from a radiography truck and after several attempts, the radiography camera was not recovered at the time of reporting. This incident posed a significant risk to public health and safety and would be reported to Congress as an AO under the revised criteria. In the FY 2019 AO event, three radiography cameras were stolen, subsequently recovered, and returned to secure storage the day of the theft. However, in this case, there was evidence of malevolent intent in gaining access to the radioactive material, resulting in a potential risk to public health and safety. Therefore, this event would also be captured as an AO under the proposed revised criteria. In

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the FY 2018 AO event, a stolen vehicle containing a radiography camera was found by law enforcement within 3 hours of the theft, and the licensee determined that the radiography camera was locked in the back of the truck and no tampering had occurred. For this event, the staff concluded that there was no radiological impact to the public or employees and as such, this type of event would not be reported as an AO under the proposed revised criteria.

In addition, criterion I.C.2 only includes radiological sabotage as defined in § 73.2 which is consistent with the regulations in 10 CFR 73, "Physical Protection of Plants and Materials." The staff proposes adding the reference for "sabotage" as defined in § 37.5 to criterion I.C.2 to better align with the regulations in 10 CFR Part 37 as it relates to category 1 and category 2 quantities of radioactive materials (Enclosure 1).

Section III.C., "Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects"

The proposed revised medical use AO criteria have two components. The first, like the current criteria, is dose-based but the new second criteria are medical-consequence-based.

As discussed in SECY-19-0088, while capturing those events of public health and safety significance, the current AO criteria also continue to identify events that are not significant from a public health or safety standpoint. The current dose-based criteria eliminated medical events that resulted in total doses just exceeding 10 Gy (1,000 rad) to tissues other than the bone marrow, the lens of the eye, and the gonads. This was accomplished by specifying a 10 Gy dose in excess of the intended dose to the treatment site. However, a retrospective review of the medical events from 2010 to 2017 that were identified as AOs (Enclosure 3) using the 2018 revised criteria show no change in the identification of those medical events previously identified as AOs. The current dose-based criteria continue to be effective in separating the medical events that are not significant from those of dose significance, but do not achieve the objective of identifying only the medical events of public health and safety significance. Therefore, the proposed revised criteria in III.C.1 are a refinement to the current dose-based criteria and are intended to assist the NRC focus on those medical events that need to be further reviewed for public health and safety significance.

Advances in the medical use of byproduct material result in the use of novel radionuclides, new administration procedures, new medical devices, and new treatment targets. These advances further complicate the evaluation of whether particular medical events have public health and safety significance, and make the use of a single dose criterion unworkable. For this reason, the proposed revised criteria III.C.2 describe how NRC will determine medical events of significant public health and safety based upon both dose and medical consequence.

All medical uses of radiation carry the probability of stochastic or even the possibility of deterministic effects. Stochastic effects may not appear for years or decades and can occur from any administrations of radiation from radiopharmaceuticals and medical devices.

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Deterministic effects manifest promptly, but still may not result in immediate radiation-induced injury. Such effects, while sometimes occurring with some delay, nevertheless provide a reasonably timely basis for assessing events of potential public health and safety significance. Therefore, the new criteria III.C.2 is not based on stochastic medical-consequences, but on deterministic effects.

The NRC staff also looked at the practices of other federal regulatory agencies to determine how they addressed medical health and safety significance. The staff reviewed the US Food and Drug Administration (FDA) adverse event definitions for drugs, biologics, and medical devices and the Department of Health and Human Services' (HHS) November 27, 2017, publication "Common Terminology Criteria for Adverse Events" Version 5.0. The FDA drug and biologic adverse event requirements are very similar to each other, and included criteria (overdose, drug abuse, drug withdrawal) that are not appropriate for NRC purposes. All FDA adverse events/reportable events included the common factor that the drug, biologic or device adverse event has or may have caused or contributed to a death or serious injury. The HHS publication provides guidance for defining adverse events for almost every part of the body. The document uses five grades to describe the severity of an adverse event. Grade 5 is death; Grade 4 is life-threatening (immediate risk of death); and Grade 3 was not immediately life-threatening, but medical or surgical intervention was needed to prevent severe or medically significant consequences. As further discussed in Enclosure 3, the NRC staff determined that events that cause death or life-threatening consequences have serious public health and safety significance. But the standard in the proposed revised criterion, impairment of a body function or damage to a body structure, better captures the subset of medical events of public health and safety significance within the larger set of medical events that meet the dose-based AO criterion.

Because the criteria are based on medical consequences, the NRC staff would need to determine responsibility for assessing whether a medical event "results in (or has a probability or resulting in) a radiation induced injury causing permanent impairment of a body function or permanent damage to a body structure …" or in a "radiation induced injury without medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure...". The staff concluded that, while licensees are responsible under 10 CFR § 35.3035(c) to identify "the effect, if any, on the individual(s) that received the administration" that resulted in a reported medical event, it is the NRC's responsibility to determine if such an event is an AO based on the information provided by the licensee, inspections, physicians (referring, licensee, or independent physicians), other health care professionals (including medical physicists and radiation biologists), and other resources. The staff recognizes that evaluating certain cases could be difficult, and could depend on expert input and professional judgment, as well as effective NRC/Agreement State coordination. Upon request, similar support to the Agreement States may be provided by a contract physician or health care professional.

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Explanation for Specific Changes:

C. Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects[16]

1. A medical event, as defined in § 35.3045 or in the specific license (based on specific 10 CFR 35.1000 licensing guidance), which results in an unintended dose that:

   (a) Is equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal to or greater than 2.5 Gy (250 rad) to the gonads; or

   (b) Exceeds, by 10 Gy (1,000 rad), the ~~expected~~ dose or dose that would have resulted from delivery of the prescribed dose, prescribed dosage or prescribed activity to any other organ or tissue from the administration ~~defined in the written directive~~; and

2. A medical event, as defined in § 35.3045 or in the specific license (based on specific 10 CFR 35.1000 licensing guidance) ~~which involves~~ that results or has high probability of resulting in:

   (a) ~~A dose or dosage that is at least 50 percent greater than that prescribed~~Radiation induced injury causing permanent impairment of bodily function or permanent damage to a body structure[17], or

   (b) Radiation induced injury in which medical or surgical intervention is needed to preclude permanent impairment of a bodily function or permanent damage to a body structure[17].

   ~~A prescribed dose or dosage that:~~

   ~~(i) Uses the wrong radiopharmaceutical or unsealed byproduct material; or~~

   ~~(ii) Is delivered by the wrong route of administration; or~~

   ~~(iii) Is delivered to the wrong treatment site; or~~

   ~~(iv) Is delivered by the wrong treatment mode; or~~

   ~~(v) Is from a leaking source or sources; or~~

   ~~(vi) Is delivered to the wrong individual or human research subject.~~

[17] NRC will use dose and medical consequence information from the licensee, inspections, physicians (referring, licensee, or consultant physicians), other professionals (e.g., medical physicist, radiation biologist), and other resources to make its AO determination.

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Changes to III.C.1.

1. The current criteria in Section III.C.1 indicate the AO must be a "medical event, as defined in § 35.3045, which results …" However, several medical uses regulated under 10 CFR 35.1000, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material," include medical event criteria based upon the unique characteristics of that medical use. While regulated under a different provision, these medical event criteria often mirror those in other subparts of 10 CFR Part 35. If there are medical event criteria in the license (generally also reflected in the licensing guidance for that particular medical use), such events may be eligible for AO reporting, as appropriate. These different medical event criteria can only become an NRC or Agreement State requirement when included in the license. Therefore, the text, "or in the specific license (based on specific 10 CFR 35.1000 licensing guidance)," was added to the criteria III.C.1 and III.C.2.

2. The current criterion III.C.1(a) has simple dose thresholds for the following three body parts: a major portion of the bone marrow, the lens of the eye, and the gonads. This criterion does not recognize the development of new medical radiation treatments that may target these body parts or nearby areas that could be expected to deliver "intended" doses at or exceeding these dose criteria. The new criterion clarifies that the dose has to be an "unintended dose" to these locations that is equal to or exceeds the specified doses.

3. Criteria III.C.1(a) and (b) are both "unintended" dose-based criteria. By adding "unintended" in III.C.1 the term "expected" is removed from criterion III.C.1(b).

4. The current criterion III.C.1(b) referred only to the expected dose "defined in the written directive." Some medical administrations resulting in medical events do not require written directives. Removal of the phrase "defined in the written directive" clarifies that a written directive is not needed for a medical event to be considered an AO. As discussed in change 3 above, the use of "unintended" in III.C.1 retains the concept of deviation from the expected dose.

5. The current criterion only considered the expected dose and did not explicitly include doses resulting from administrations based on dosages and activity instructions. Because criterion III.C.1 is still dose-based (the unintended dose is measured in Gy or rad), the criterion would be revised to read "dose or dose that would have resulted from delivery of the prescribed dose, prescribed dosage or prescribed activity."

Changes to III.C.2.

1. The expanded definition of a medical event would be revised to include criteria specific to a 10 CFR 35.1000 medical use authorizations consistent with Criterion III.C.1.

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2. The current criterion III.C.2 unnecessarily repeats regulatory medical event criteria and was deleted for this reason. NRC will continue to include the appropriate medical event criteria in future reports of particular abnormal occurrences.

3. The new criterion III.C.2 introduces a medical-consequence standard to capture medical events of public health and safety significance.

4. The proposed revised criterion would be based on radiation induced injury, but some injuries will not manifest themselves immediately and may take some time to manifest. To ensure NRC AO reports capture those events with public health and safety significance to Congress in a timely manner, the phrase "high probability" was included in the criterion.

5. Some radiation induced injuries will naturally heal, and the NRC generally does not consider these to be of public health and safety significance. This is why NRC would add the condition that the radiation induced injury causes permanent impairment of bodily function or permanent damage to a body structure.

6. Consistent with the revised focus on dose as well as injury, to capture those radiation induced injuries that would have caused permanent impairment of a bodily function or permanent damage to a body structure absent medical or surgical intervention, criterion III.C.2(b) would be added.

7. The final determination of whether criterion III.C.2(a) or (b) is met is made by the NRC. The NRC has the responsibility to determine when medical events are AOs. The footnote clarifies that the NRC will make this determination based on dose and medical consequence information provided by the licensee, inspections, physicians (referring, licensee, or independent physicians), other health care professionals (including medical physicist and radiation biologists), and other resources.

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Summary of Retrospective Review of the Medical Events reported to NRC between 2010 and 2020 and to Congress as AOs

The table below displays the medical Abnormal Occurrence (AO) events reported to Congress and medical events reported to the NRC per Fiscal Year (FY), number that resulted in pre-2018 AO criteria, under the revised 2018 criteria and under the proposed medical-consequence criteria.

FY[1]	Medical AOs reported to Congress in FY[1]	Medical Events reported to NRC in FY[1]	Medical events in FY[2] meeting pre-2018 AO criteria[1]	Medical events in FY[2] meeting 2018 AO criteria	Medical events[2] with a high possibility of meeting the Proposed medical-consequence AO criteria	Medical events[2] – undetermined if meeting the Proposed medical-consequence AO criteria
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7
2010	12	49	18	18	1	1
2011	19	58	14	14	5	2
2012	19	48	15	15	4	0
2013	8	43	7	7	3	2
2014	12	46	11	11	3	2
2015	16	57	13	13	5	2
2016	8	50	8	8	2	1
2017	11	43	10	10	0	0
2018	9	48	NA	8	2	1
2019	7	56	NA	7	1	1
2020	8	52	NA	8	3	0
Total	129	550		119	29	12

[1] Individual AOs may not be reported to Congress in the year that the medical event was reported to NRC.
[2] If a reported medical event met the medical event criteria in the year it was reported, it was not reevaluated to see if it meets the medical event criteria for a subsequent year or under the current AO criteria.

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Discussion:

The above table provides information on medical events and AOs by the fiscal year (FY) identified in Column 1. The medical AOs NRC reported to Congress by FY are in Column 2. However, the individual AOs were not necessarily reported to Congress in the year in which the corresponding medical event was reported to NRC. Therefore, the table includes the number of medical events reported to NRC by FY (Column 3). Column 4 shows the number of these medical events that were later determined to be AOs under the criteria in place from FY 2010 to 2017.

In 2017, the NRC approved new medical event criteria for use from 2018 to present. Both criteria are based only on dose. Column 5 includes the medical events that met the new 2018 AO criteria. The table shows that although the criteria changed in 2018, all the AOs determined to be AOs under the pre-2018 criteria also met the 2018 to present criteria. The table also shows that of the 550 medical events reported between 2010 and 2020, approximately 22 percent (119) were determined to be more dose-significant than the others, but as discussed in SECY-19-0088, these 119 medical events still captured events that are not significant from a public health or safety standpoint.

Therefore, while effective in differentiating between non-significant medical events and dose - significant events, the current criteria are not effective in only identifying those medical events of significance from the standpoint of public health and safety. The second part of the retrospective review was to compare the text of each medical event over the 10-year period reported as an AO with the new proposed medical-consequence criteria. Each medical event was coded as not meeting the new criteria, high possibility of meeting the new criteria (Column 6), or that the staff could not determine it would or would not meet the new criteria (Column 7).

Retrospective Review of Specific AO Text:

The NRC medical event reporting requirements in Title 10 of the *Code of Federal Regulations* (CFR) Part 35.3035(c) require licensees to identify "the effect, if any, on the individual(s) that received the administration" that resulted in a reported medical event. This general criterion to describe the effect on the patient resulted in the need to evaluate a spectrum of statements captured in the medical event AO reports to determine if they would qualify as AOs under the proposed revised criterion. The coding of an event in one of the three categories already described is subjective because the more definitive patient criteria of radiation induced injury did not exist when each event was determined to be an AO. Although the information required in the medical event report has not changed, it is expected that additional information may be requested to clarify future determinations of whether a medical event is also an AO if these revisions go into effect.

Reports coded as "not meeting the proposed criteria" ranged from general statements that the medical event would not have "an adverse" or " a significant medical" effect on the patient to more detailed descriptions such as "… faint erythema over the lumpectomy site and no

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evidence of erythema where the source had been in contact with the skin. Later ulcerations developed and healed without further complication."

The reports coded as "undetermined" either lacked information on the effect on the patient or included information that did not permit a definitive determination. These reports also included a range of statements. Many of these event descriptions contained statements that the patient will continue to be monitored or that there was a non-quantified possibility of transient or permanent medical effects. Examples of these statements include: "unable to perform a dose assessment of the affected tissue due to the radiation oncologist's inadequate post procedure seed implant records;" "no unintended medical effects have been identified … the patient will continue to be medically monitored;" "the likely effect would be possible transient numbness to the right side of the patient's face;" and there "is the potential generation of a duodenal ulcer caused by the radiation …the licensee is treating the patient to minimize radiation damage to the duodenum and will continue to monitor the patient's condition." In the future, with additional information, these types of statements may be further clarified so that a similar medical event can be coded as either "not meeting the proposed criteria" or elevated to confirmed AO.

If an event indicated radiation induced injury without an indication of naturally healing and thus a higher possibility of meeting the new criteria, it was coded as "possibly meeting the new criteria." Examples of events with this coding included: "this elevated dose may result in an increased risk of atrophy to the left lobe of the liver;" "after consultation with international and domestic experts, the patient was administered the radio-protective agent amifostine. The licensee concluded that the event may result in unintended, permanent functional damage and some form of future medical intervention was likely needed;" "the patient also experienced rectal wall thickening, urethral stricture, and ulceration of the anterior rectal wall, as confirmed by a colonoscopy;" "the patient was admitted because of severe anemia and suspected gastrointestinal bleeding, … endoscopy revealed a duodenum lesion and an ulcer that had developed seemingly because of microspheres migrating to the stomach (wrong treatment site);" and "potential short term effects include progression of these skin reactions and possible urinary and rectal irritation. Long term effects may include thickening of the skin and the mucosa, development of scar tissue and urinary track and rectal issues." These events indicate radiation induced injury. Under the proposed revised criteria, similar events would be coded with greater certainty as meeting or not meeting the new criteria because additional information related to potential permanent impairment would be provided.

Conclusion:

This retrospective review indicates that some physicians included descriptions in their required written medical event reports that provided information on radiation induced injury, if the injury healed without intervention, if medical or surgical intervention was needed, and the possibility of permanent injury or loss of bodily function. In many cases it is not possible to determine whether the medical event would meet the proposed criteria. However, because 10 CFR §

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35.3035(c) requires reporting the effect of the administration when a medical event occurs, in implementing the revised AO criteria, future reports will and should include sufficient information on health effects for the NRC to make the medical consequence determination under the revised AO criteria, as appropriate.

The NRC staff aimed to develop revised medical event AO criteria that more accurately reflect significant public health and safety concern. The staff, based on its retrospective review of past AO events, concludes that by combining a dose-based element with a medical-consequence-based element, the new proposed combined criteria are able to better identify those medical events that are of significant public health and safety.

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