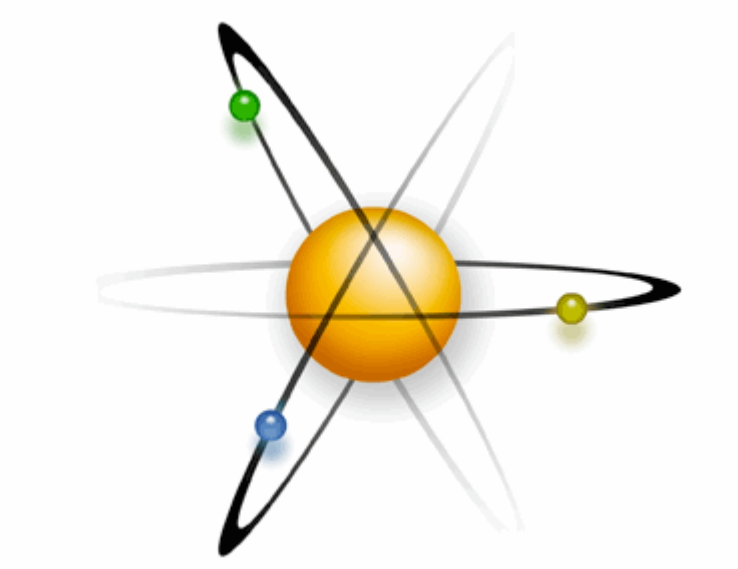
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

SPRING 2023 MEETING
MAY 15-16, 2023

Meeting Handout



MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
May 15-16, 2023

One White Flint North Building, 11555 Rockville Pike, Commissioner's Hearing Room,
Two White Flint North Building, 11545 Rockville Pike, T3-D06
North Bethesda, Maryland 20852

NOTE: Sessions of the meeting may be closed pursuant to 5 U.S.C. 552(b) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACMUI; information the release of which would constitute a clearly unwarranted invasion of personal privacy; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and disclosure of information which would risk circumvention of an agency regulation or statute.

Monday, May 15, 2023
OPEN SESSION

	1. Opening Remarks Mr. Einberg will formally open the meeting and Mr. Williams will provide opening remarks.	**C. Einberg, NRC** **K. Williams, NRC**
	2. Old Business Dr. Valentin-Rodriguez will review past ACMUI recommendations and provide NRC responses.	**C. Valentin-Rodriguez, NRC**
	3. Open Forum The ACMUI will identify medical topics of interest for further discussion.	**ACMUI**
8:30 – 11:45	**4. Medical Related Events** Mr. DiMarco will provide an update on recent medical events.	**D. DiMarco, NRC**
	5. Revisions to the Abnormal Occurrence Criteria Mr. Flora will provide an update on the limited revisions to the NRC's abnormal occurrence criteria.	**R. Flora, NRC**
	6. Medical Team Updates Dr. Valentin-Rodriguez will provide updates on the Medical Team's recent initiatives and ongoing efforts.	**C.Valentin-Rodriguez, NRC**
11:45 – 1:00	**LUNCH**	
	7. Training & Experience for All Modalities Dr. Jadvar will provide the Training & Experience for All Modalities subcommittee report on the potential impacts of ABR's termination request and their review of the NRC's process for recognition of medical specialty boards.	**H. Jadvar, ACMUI**
1:00 – 3:00	**8. Extravasations Rulemaking** Ms. Wu will provide an update on the NRC's rulemaking that will require reporting of certain nuclear medicine injection extravasations.	**I. Wu, NRC**
	9. ACMUI Reporting Structure Dr. Valentin-Rodriguez will provide an overview of the current reporting structure. Members will discuss the reporting structure of the Committee and provide feedback to the NRC.	**C. Valentin-Rodriguez, NRC**

3:00 – 3:15	**BREAK**	
	10. Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials Dr. Harvey will discuss the subcommittee's review of the NRC's draft proposed rule on Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials.	**R. Harvey, ACMUI**
3:15 – 4:45	**11. Open Forum** The ACMUI will discuss medical topics of interest previously identified.	**ACMUI**
	12. Administrative Closing Dr. Valentin-Rodriguez will provide a meeting summary and propose dates for the fall 2023 meeting.	**C. Valentin-Rodriguez, NRC**

BREAK (public portion ends)

Tuesday, May 16, 2023
CLOSED SESSION

9:00 – 9:30	**1. ACMUI Member Roles and Responsibilities**
9:30 – 10:00	**2. NRC Staff Interactions with ACMUI**
10: 00 – 11:00	**3. ACMUI Working Session: Biennial Evaluations**
11:00 – 12:00	**4. Meet and Greet with NMSS Leadership and Medical Team**

ADJOURN

2019 ACMUI Recommendations and Action Items

	ITEM	DATE	STATUS		Target Completion Date for NRC Action
18	The ACMUI endorsed the Evaluation of Extravasations Subcommittee Report, as amended, to note that under future revisions to Part 35 rulemakings, extravasations be captured as a type of passive patient intervention in the definition of patient intervention.	9/10/2019	*Accepted*	Propose to close	Winter 2022

2020 ACMUI Recommendations and Action Items

	ITEM	DATE	STATUS		Target Completion Date for NRC Action
4	The ACMUI endorsed the Patient Intervention subcommittee report, as presented, and the recommendations provided therein to re-interpret current definition of patient intervention and to report medical events resulting from patient intervention which result in unintended permanent functional damage under 10 CFR 35.3045(b).	3/30/2020	*Accepted*	Propose to close	Winter 2022
11	As part of the Non-Medical Events report, the ACMUI recommended to the NRC staff and/or NMP to evaluate the issue of detection of short-lived medical isotopes in municipal waste (waste from nuclear medicine patients that might be triggering the landfill alarms) and provide some level of guidance, best practices, or additional instructions.	9/21/2020	*Accepted*	Open	Fall 2023

2021 ACMUI Recommendations and Action Items

	ITEM	DATE	STATUS		Target Completion Date for NRC Action
6	The ACMUI endorsed the Extravasation Subcommittee report, as amended, to support option 4 of the Subcommittee Report.	9/02/2021	*Accepted*	Propose to close	Winter 2022
7	The ACMUI formed a new subcommittee on the Liberty Vision Y-90 Manual Brachytherapy source. The subcommittee is expected to provide a draft report and any recommendations at the spring 2022 ACMUI meeting.	10/04/2021	*Accepted*	Open	Fall 2023
10	The ACMUI endorsed the Radionuclide Generator Knowledge and Practice Requirements Subcommittee Report and the recommendations provided therein.	10/04/2021	*Accepted*	Open	March 2026
15	The ACMUI endorsed the ACMUI RG. 8.39 Subcommittee report on CivaDerm and the recommendations therein.	12/15/2021	*Accepted*	Open	Summer 2023
16	The ACMUI endorsed the ACMUI RG. 8.39 Subcommittee report on the proposed revision to RG 8.39 and the recommendations therein.	12/15/2021	*Accepted*	Propose to close	Spring 2023

2022 ACMUI Recommendations and Action Items

	ITEM	DATE	STATUS		Target Completion Date for NRC Action
1	As discussed during the spring 2022 ACMUI meeting, a suggestion was made for the ACMUI to review the rulemaking plan for the ongoing NRC effort to revise Appendix B to Part 30—Quantities of Licensed Material Requiring Labeling.	4/5/2022	*Accepted*	Propose to close	Spring 2023
4	The ACMUI endorsed the Y-90 microsphere ME Subcommittee report and the recommendations therein.	12/5/2022	*Accepted*	Open	Fall 2024
5	The ACMUI endorsed the EMT/Rb-82 generator rulemaking subcommittee report on the draft regulatory basis and the recommendations therein.	12/5/2022	*Accepted*	Propose to close	Summer 2023
6	The ACMUI established two subcommittees: one to create generic process checklists to be used during medical administrations and one to review the DFA draft proposed rule. The ACMUI also reestablished the Nursing Mothers guidelines to update the 2019 guidelines.	12/5/2022	*Accepted*	Open	Fall 2023
7	The ACMUI tentatively scheduled its 2023 spring meeting for May 15-16, 2023. An in-person meeting is expected for these dates.	12/5/2022	*Accepted*	Propose to close	Spring 2023

OPEN FORUM

(No Handout)

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

Status of Medical Events FY 2022

Daniel DiMarco
Medical Radiation Safety Team
May 15, 2023

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.

Medical Events FY 2017 - 2022

	FY17	FY18	FY19	FY20	FY21	FY22
35.200	0	0	1 (8*)	0	4	0
35.300	4	2	9	2	10	10
35.400	7	11 (13*)	5	6	4	1
35.600	8 (14*)	10	9 (10*)	13	5	11 (40*)
35.1000	24	25 (26*)	32	27	41	34
Total	43	48	56	48	64	56

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

Medical Events 2022

35.200	**Medical events**	**0**

Medical Events 2022

35.300 Medical events	**10**
Lutetium-177	4
I-131 NaI	3
Ra-233	2
Ac-225	1

35.300 I-131 NaI

- Patient overdose [210490]
  - Patient prescribed 0.074 GBq (2mCi), received 5.62 GBq (152 mCi)
  - Patient intended to receive 5.55 GBq (150 mCi), signed in medical record
  - Error in computer-generated written directive
  - No harm because intended treatment was administered
  - Corrective actions included changes to computer-generated written directive and procedure changes to existing timeout process

35.300 I-131

- Patient underdose [210455]
  - Prescribed 3.7 GBq (100 mCi), administered 2.9 GBq (78.5 mCi)
  - Therapeutic portion of a sponsored study protocol
  - Fixed activity administration limited by kidney dose, no reliable dose estimate for the prostate
  - Root cause determined to be inadequate training on protocol
  - Corrective actions included additional training
  - No adverse impacts were expected
  - Follow-up doses were cancelled due to proximity to kidney dose constraints

35.300 I-131

- Patient underdose [210448]
  - Patient prescribed 925 MBq (25 mCi), received 370 kBq (10 μCi)
  - Administered I-131 capsule, was unable to swallow and pill broke down in mouth
  - Capsule was removed and taken to safe room
  - Some removed pharmaceutical leaked, leading to a contamination incident
  - Second administration of liquid I-131 attempted the next day, patient also failed to swallow
  - Dose from first administration estimated by bioassay
  - Corrective actions included having patients swallow a placebo pill prior to administration
  - No persons were determined to be contaminated; decontamination of surfaces was successful

35.300 Lu-177 Lutathera

- Patient overdose [220331]
  - Prescribed 3.7 GBq (100 mCi), administered 7.62 GBq (206 mCi)
  - Patient had kidney disease, requiring the smaller dosage
  - Administering tech did not receive the written directive from NM Dept
  - Pharmacy tech drew typical dosage of 7.4 GBq (200 mCi), did not consult written directive
  - Root cause was determined to be failure to follow established protocols and lack of communication within department
  - Corrective actions included a “daily huddle” to communicate key information about the day’s therapy patients
  - Additionally, the secondary verification now requires a physical signature on the written directive
  - Patient will be followed to assess for kidney damage

35.300 Lu-177 Lutathera

- Patient overdose [220328]
  - Prescribed 3.7 GBq (100 mCi), administered 7.62 GBq (206 mCi)
  - Third of four treatments, previous treatments also prescribed 3.7 GBq (100 mCi) due to reduced creatinine clearance
  - Delay in treatment due to suspension of radioisotope production
  - Resulted in adequate creatinine levels for the treatment, doses to non-target tissues was in line with parameters for a standard treatment
  - Final treatment was planned to be either a full or half dose, depending on patient tolerance
  - Written directive was updated to improve verification process of dose measurement

35.300 Lu-177 Lutathera

- Patient underdose [220128]
  - Patient prescribed 7.62 GBq (206 mCi), received 1.48 GBq (40 mCi)
  - Two minutes after infusion, leak was noticed in line
  - Procedure stopped and vial and tubing assayed
  - Wipe tests showed no patient contamination
  - Room was surveyed and appropriately decontaminated
  - Root cause was equipment failure, corrective actions were implemented
  - No clinical impact or risks to the patient

35.300 Lu-177

- Patient underdose [220114]
  - Patient prescribed 7.4 GBq (200 mCi), received 0.052 GBq (1.4 mCi)
  - Vial lost pressure during treatment
  - Remedial measures attempted but failed
  - No contamination found
  - No adverse effects noted

35.300 Ra-223

- Patient overdose [220338]
  - Patient prescribed 2.13 MBq (57.5 µCi), received 6.84 MBq (184.9 µCi)
  - Clerical error in written directive, patient received intended dose

35.300 Ra-223 Xofigo

- Patient underdose [220340]
  - Patient prescribed 7.83MBq (211.6 µCi), received 5.92 MBq (160 µCi)
  - Leakage occurred in three-way stopcock during administration
  - Administered dose estimated by measuring the leaked radiopharmaceutical
  - Root cause was determined to be incorrect cap used on the unused port
  - Corrective actions included procedure revisions to prevent leakage and additional training
  - No harm is expected to the patient

35.300 Ac-225

- Patient underdose [210503]
  - Patient prescribed 5.55 MBq (150 μCi), received 4.22 MBq (114 μCi)
  - Clinical trial for prostate cancer
  - Accidental discharge onto absorbent pad
  - Root cause determined to be the recession of the connection point into the tungsten shield, hindering operation of the three-way stopcock
  - AU removed connection without required three saline flushes
  - Corrective actions included retraining of all AUs, refresher training on written directives, and acquisition of an alpha detector to survey for contamination

Medical Events 2022

35.400 Medical events	**1**
Eye Plaque	1

35.400 I-125 Eye Plaque

- Patient underdose [210459]
  - Prescribed 8,500 cGy (rad), received 1,695 cGy (rad)
  - Plaque held 30 seeds with an activity of 49.21 MBq (1.33 mCi) in each seed
  - Plaque dislodged while patient rubbed eye
  - Plaque placed in lead pouch and returned to AU
  - No corrective actions taken

Medical Events 2021

35.600 Medical events	**11**
HDR	10
PDR	1

35.600 HDR

- Patient overdose [220167]
  - 333 GBq (9 Ci) I-192 HDR Unit
  - Prescribed 10 HDR treatments, following four treatments the licensee noticed some source catheters had been mislabeled
  - Planned skin dose was 26.5 Gy (2650 rad), after adjustments the dose to skin was 48.4 Gy (4840 rad)
  - No adverse effects expected but patient will have more frequent follow-up
  - Root cause determined to be human error and lack of proper catheter identification
  - Corrective actions included procedure updates to emphasize catheter identification and modification of planning process to include an additional review by a second physicist
  - Staff also received additional training

35.600 HDR

- Patient underdose [220186]
  - 370 GBq(10 Ci) Ir-192 HDR unit
  - 2 patients both prescribed 4 fractions of 7 Gy (700 rad) for a total of 28 Gy (2800 rad)
  - First patient had an underdose in fraction 2 of 4, only 79.1% of he fraction was delivered
  - Second patient had an underdose in fraction 4 of 4, only 54.4% of the fraction was delivered
    - Additionally, this patient received a 48% greater dose to the rectum for this fraction, resulting in a 15.4% greater dose to the rectum for the full treatment

35.600 HDR

- Patient underdose [220186] (cont.)
  - Radiation therapist replaced a catheter with one that was an incorrect length
    - Procedures required a blue catheter with a 1377 mm length, but the new blue catheters are longer than this and must be trimmed down to the correct length
  - Corrective actions included procedure modifications to ensure the correct catheter is of appropriate length, and additional training
  - Patient one had modifications to the rest of the treatment to compensate for the underdose, patient two had no adverse effects

35.600 HDR

- Patient underdose [210482]
  - 277.5 GBq (7.5 Ci) Ir-192 HDR unit
  - Patient prescribed 1400 cGy (rad), administered 1020 cGy (rad)
  - Error message “8C.2 – Dummy park switch or drive failure” displayed during treatment after first 15 channels were delivered
  - Field service engineer suggested reboot of system, not successful
  - AU stopped treatment to avoid leaving patient under general anesthesia, leaving remaining four channels untreated

35.600 HDR

- Patient underdose [210512]
  - 221.26 GBq (5.98 Ci) Ir-192 HDR unit
  - Prescribed 1500 cGy (rad), received 50 cGy (rad)
  - Patient was treated without issue through first channel
  - Error at the start of the second channel, indicating the source position slipped at 0.0 cm mark
  - Treatment paused and test wire was run, no errors indicated
  - Second attempt at treatment returned the same error, treatment was cancelled
  - Source was verified to be in the unit and no additional dose was delivered to the patient or staff
  - Service engineer determined a hardware issue with the active source encoder, which serves as a second check for the movement of the source
  - Encoder replaced, HDR unit determined operational

35.600 HDR

- Wrong site [220085]
  - 237.58 GBq (6.421 Ci) HDR unit
  - Patient intended to receive 600 cGy (rad) to lower third nasal dorsum
  - Patient prescribed 600 cGy (rad) to right nasal sidewall
  - No adverse effects expected

35.600 HDR

- Wrong site [220261]
  - HDR Unit
  - Prescribed 3600 cGy (rad) to the skin of the left scalp
  - Physician misidentified the treatment site, photos taken after biopsy but had healed when trying to identify prior to treatment
  - Potential consequences determined to be potential to develop skin cancer at the treated site in 20-30 years and recurrence of the cancer at the untreated site

35.600 HDR

- Wrong site [220261] (cont.)
  - Patient was offered additional treatment to the carcinoma. But chose observation by dermatologist
  - Corrective actions included creation of an HDR planning policy for dermal brachytherapy
  - Updated commitment to policy to state that HDR skin cancer sites will be reviewed at a peer review meeting before treatment
  - Better photographs of the treatment site will be taken and ambiguous information will require additional verification

35.600 HDR

- Wrong site [220275]
  - 177.6 GBq (4.8 Ci) I-192 HDR Unit
  - Patient has two lesions on the lower right leg
  - First was treated using SBRT without incident
  - Second prescribed 4000 cGy (rad) over 8 fractions
  - First fraction, 500 cGy (rad), unintentionally delivered to the first lesion
  - Discovered when the patient noticed the planning circle had been drawn over the first lesion before the second fraction
  - No adverse effects are expected

35.600 HDR

- Wrong site [220275] (cont.)
  - Root cause was determined to be human error, particularly failure to notice the change in positioning from supine to prone
  - Contribution factors were the proximity of the 2 lesions (1.5 in apart) and that the second lesion was not present during the previous SBRT treatment
  - Corrective actions included adding a pretreatment step for multiple, close lesions, asking the patient to point to the treatment site, and using more verification images of the treatment site

35.600 HDR

- Wrong site [210537]
  - 277 GBq (7.485 Ci) Ir-192 source
  - Prescribed 2100 cGy (rad), delivered in three 700 cGy (rad) treatments
  - First fraction delivered
  - Some point after patient experienced complications from a hysterectomy, treated at a different hospital
  - Did not return for other treatments
  - Oncologist at new hospital determined that the first treatment was off by 3 cm
  - Colon and bowel received dose of 700 cGy (rad)
  - Corrective actions included procedure modification to require CT imaging/review after insertion of HDR applicators

35.600 HDR

- Wrong site [220026]
  - 436.97 GBq (11.81 Ci) Ir-192 HDR unit
  - Patient received a single 250 cGy (rad) fraction to the left hand, instead of the right hand as prescribed
  - Corrective actions included immediate discussion with all clinical staff to verify correct anatomical treatment site regarding all prescriptions

35.600 HDR

- Wrong site [220308]
  - 370 GBq (10 Ci) I-192 HDR Unit
  - Deviation in transfer tube by 2.9 cm discovered, affecting 27 patients
  - Dose to the unintended tissue was determined by recreating the intended plan and comparing to a transfer tube shifted plan
  - Resulted in 267 cGy (rad) of additional dose to unintended tissues per fraction
  - Investigation and corrective actions still ongoing

35.600 PDR

- Patient underdose [220224]
  - 37 GBq (1 Ci) PDR unit
  - Three patients
    - 2982 cGy (rad) prescribed, 256.7 cGy (rad) delivered
    - 36.21 cGy (rad) prescribed, 12.07 cGy (rad) delivered
    - 37.28 cGy (rad) prescribed, 16.72 cGy (rad) delivered
  - Discrepancy between measured treatment distance and treatment plan
  - Root cause determined to be erroneous manual entry in reference table (1248 mm entered vs. 1448 mm intended)
  - Corrective actions included root cause analysis, procedure modification, and additional reference table verification

Medical Events 2022

35.1000 Medical events	**34**
GSR	2
Y-90 Microspheres	
– TheraSphere™	23
– SIR-Spheres®	7

35.1000 Gamma Knife

- Wrong site [220241]
  - Patient prescribed between 20 and 21 Gy (2000 to 2100 rad) to four lesions in the brain
  - Post treatment, discovered that the targeting had been off by 0.5 cm for all lesions
  - Delivered dose to lesions between 8 and 15 Gy (800 to 1500 rad)
  - Max dose range to unintended healthy tissue was 21.82 to 27.09 Gy (2182 to 2709 rad)

35.1000 Gamma Knife

- Wrong site [220241] (cont.)
  - Root cause was shifting of coregistration of images between intended target and treatment parameters
    - Discovered after surgery
  - No adverse effects are expected but patient will be monitored
  - Corrective actions included updated treatment procedures to include review and approval of treatment plan by two of three team members that involve coregistration of CT/MRI images

35.1000 Gamma Knife

- Wrong site [220484]
  - Patient treated for 10 brain lesions, patient fell asleep during treatment of first 4 lesions
  - Patient woke up for the fifth treatment but no sufficient movement was recorded to stop/delay treatment
  - Treatment later paused to allow the patient to use the restroom, during which the therapist noticed the frame had moved from its original position
  - Remainder of the treatment was cancelled, new CT was performed, and new treatment plan was developed for the remaining 4 lesions, which were treated without incident
  - Review of the treatment indicated that 4 lesions were treated initially, 2 followed the patient waking up, and the remaining 4 were treated after the re-planning

35.1000 Gamma Knife

- Wrong site [220484] (cont.)
  - Potential effects were determined on a most likely and worst-case scenario
    - Most likely – only 2 lesions affected by movement
    - Worst-case – 6 initial lesions affected by movement
  - In the most likely scenario, the two lesions received slightly more dose due to a slightly higher volume of brain tissue exposed and there was no effect on the other lesions
  - In the worst-case scenario, two lesions would be underdosed by over 50% and would have significantly high risk of recurrence
  - The patient has been followed and has shown no detrimental effects from this event
  - This event is still under investigation

35.1000 TheraSphere™

- Y-90 TheraSphere™ overdose [220181]
  - Patient prescribed 2.228 GBq (60.22 mCi), received 2.84 GBq (76.7 mCi)
  - When administering microspheres to three liver segments, it was determined that the segment had been misidentified due to variant anatomy
  - Segment 7 received more dose than expected but all three targets had received an appropriate segementectomy dose
  - Root cause was determined to be failure to identify variant anatomy during treatment
  - Corrective actions included secondary review of pre-treatment mapping and angiography of any administration where the location of the catheter is questioned
  - If this is not effective, the AU will perform a 3d cone beam CT to confirm the area to be treated
  - No adverse effects were expected

35.1000 TheraSphere™

- Y-90 TheraSphere™ overdose [210494]
  - Patient prescribed 2 administrations to different segments of the liver, 1 GBq (27 mCi) and 2.72 GBq (73.4 mCi)
  - Administered 2.18 GBq (59 mCi) and 4.4 GBq (119 mCi) respectively
  - The doses had been ordered with an incorrect calibration date
  - Root cause was determined to be a failure to confirm the calibration date and a failure to check the that the prescribed dose matched the measured dose during pre-treatment checks
  - Patient was followed and no adverse effects were noted
  - Corrective actions included updating Y-90 worksheets to add a new verification of dose-in-hand rather versus the written directive, and an update to the dose ordering process requiring a second person to give their signature
  - Personnel were trained on these new procedures

35.1000 TheraSphere™

- Y-90 TheraSphere™ overdose [220207]
  - Patient prescribed 1.94 GBq (52.43 mCi), received 2.81 GBq (75.95 mCi)
  - Patient intended to receive 2 vials of microspheres for the administered dose
  - WD erroneously accounted for only one vial
  - Administered activity was within 2% of planned activity
  - Root cause was determined to be human error
  - Corrective actions included personnel training and procedure updates

35.1000 TheraSphere™

- Y-90 TheraSphere™ overdose [220173]
  - Patient prescribed 0.355 GBq (9.6 mCi), received 2.17 GBq (58.6 mCi)
  - Two patients were due to receive Y-90 treatment on the same day
    - Patient A with 2 vials, Patient B with 3 vials
  - Patient A was prescribed 0.355 GBq (9.6 mCi) and 1.3 GBq (35.2 mCi), but the first vial was mistakenly swapped with one of Patient B's vials
  - The WD prescribed 12,000 cGy (rad) to segments 2 and 3 but received 73,660 cGy (rad)
  - This dose was considered clinically acceptable, and no adverse effects are expected
  - Patient B's treatment was cancelled

35.1000 TheraSphere™

- Y-90 TheraSphere™ overdose [220173] (cont.)
  - Corrective actions included requiring a signed verification of dose activity by two techs, with a temporary requirement that one be a supervisor or manager
  - Additionally, all dose vials are now required to be re-verified in the vent of handoff between certified NMTs
  - Y-90 standard operating procedure was revised and all staff and Aus were trained on the updates
  - For 90 days following the event, a supervisor checked the cart, documentation, and calibration instrumentation for accuracy prior to transport to the IR suite
  - Monthly audits occurred for 90 days to determine effectiveness of these actions, after which quarterly audits continued

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [210491]
  - Patient prescribed 1.3 GBq (35.1 mCi), received 0.533 GBq (14.4 mCi)
  - Vial septum failed under pressure during administration
  - No effects were expected
  - Root cause was determined to be failure to develop, implement, and maintain procedures
  - Corrective actions included revision of procedures to specify the correct needle gauge and revision of emergency procedures

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [210480]
  - Patient prescribed 1.66 GBq (44.8 mCi), received 0.692 GBq (18.7 mCi)
  - Physician noted that there was greater resistance during administration but no stoppage occurred due to intervention or patient
  - Tubing and connections were checked, no cause for the resistance was found
  - Overflow bottle did overflow but no activity was measured
  - Dose rate at vial was zero after administration and no contamination was found

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [210480] (cont.)
  - Investigation found that microspheres had built up at the distal and proximal ends of the catheter, but no reason could be found
  - Manufacturer noted that the catheter was within the recommended size
  - Corrective actions included more flushes during treatment

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220054]
  - Patient prescribed 1.45 GBq (39.24 mCi), received 1.03 GBq (27.72 mCi)
  - Treatment proceeded without incident, but post-treatment survey of waste revealed 0.43 GBq (11.52 mCi) of Y-90
  - No contamination was detected
  - No adverse effects are expected

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [210529]
  - Patient prescribed 4.08 GBq (110.27 mCi), received 2.57 GBq (69.46 mCi)
  - Treatment proceeded without incident
  - Post-treatment surveys revealed residual activity and gave estimates of the administered dose
  - Root cause was determined to be flow issue in the microcatheter, causing the microspheres to precipitate out
  - No adverse effects to the patient are expected

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220182]
  - Patient prescribed 379.99 MBq (10.27 mCi), received 260.11 MBq (7.03 mCi)
  - AU noticed sluggish flow during first saline flush, possibly due to kinking in the microcatheter
  - No contamination was identified, and the AU was satisfied with the dose delivered
  - Root cause was determined to be small treatment volume and small vessel treated
  - More than 30 psi is required to push microspheres into small vessels, but the built-in pressure valve did not apply pressure greater than 30 psi
  - No adverse effects were expected

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220264]
  - Patient received only 26% of prescribed dose
  - Treatment went according to plan, post-treatment surveys revealed that microspheres did not come out of the tubing as designed
  - All proper procedures were followed, no kinks in tubing could be identified, and the AU had used a larger catheter than required
  - Over 70% of the microspheres remained in the delivery device
  - No root cause could be identified but investigations determined that the most likely cause was equipment failure
  - No corrective actions were identified

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220390]
  - Patient prescribed 44,000 cGy (rad), received 35,180 cGy (rad).
  - During preparation, oncology nurse expelled some liquid onto gauze to remove bubbles from the treatment tubing
  - The loss of activity resulted in a smaller delivered activity
  - No adverse effects were expected, and no additional dose was needed
  - Investigation determined that proper procedure had been followed and it was not clear whether the vent was caused by human error or product defect

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220387]
  - Patient prescribed 1.27 GBq (34.4 mCi), received 111 MBq (3 mCi)
  - Procedure was halted prematurely, and surveys of the waste and room were taken
  - No contamination was found, and microspheres were observed clustered in the hub
  - Correct microcatheter was used
  - Waste survey was used to approximate dose delivered
  - Root cause was determined to be microsphere clumping between lines E and D in the kit

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220410]
  - Patient prescribed 1.77 GBq (48 mCi), received 1.05 GBq (28 mCi)
  - Microspheres clumped in catheter and AU was unable to administer the full dose
  - Root cause was determined to be a microcatheter with a curved tip that ended up at the vessel wall, blocking the flow of microspheres
  - Corrective actions included discontinuing use of that type of microcatheter

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [210493]
  - Patient prescribed 1.26 GBq (34.1 mCi), received 0.895 GBq (24.2 mCi)
  - Surveys after the administration noted that microshperes were held up in the catheter
  - Root cause was determined to be clumping of microspheres in the catheter due to problems in the procedure
  - A copy of IN-19-12 was provided to understand the issue and help prevent future incidents

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [210486]
  - Patient prescribed 3 GBq (81.08 mCi), received 1.96 GBq (52.90 mCi)
  - Surveys of the container revealed a higher than expected dose after the administration
  - Delivery kit was shipped to manufacturer after decay
  - Root cause was determined to be intentional use of a smaller catheter than advised (0.3mm), resulting in microspheres being held up in the line
  - Physician determined that the dose delivered was effective
  - No corrective actions were taken

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [210500]
  - Patient prescribed 809.93 MBq (21.89 mCi), received 509.86 MBq (13.78 mCi)
  - One of four treatments to different lobes of the liver
    - Three other treatments had no complications
  - Physician attempted to use 2.0 Fr. Truselect microcatheter for an hour to access artery but was unsuccessful
  - Fell back on a 1.7 Fr. Echelon microcatheter, where some of the microspheres were held up in the smaller catheter
  - Other treatment options were considered, but the decision to use the smaller catheter was determined by the physician to be medically necessary
  - No adverse effects are expected and no corrective actions were put in place

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220039]
  - Patient prescribed 1.93 GBq (52.16 mCi), received 0.49 GBq (13.24 mCi)
  - Treatment was prematurely terminated due to unwinding of male Leur lock connector
  - A second WD was created to compensate for the underdose and this treatment was successful
  - Information of this event was circulated to all impacted licensees
  - Root cause was determined to be a defective Leur lock
  - The event was not reported initially due to insufficient WD procedures
  - Corrective actions included casing use of the affected administration set

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220021]
  - Patient was successfully administered two doses of microsphere but the third only administered 5% of the dose
  - The microspheres were caught up in the tubing from the vial

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220127]
  - Patient prescribed 2.93 GBq (79.19 mCi), received less than 1% of prescribed
  - AU noticed resistance during administration and halted the treatment
  - Microspheres were observed clumped in the first 2 in of the delivery catheter
  - Second dose ordered and delivered successfully
  - No contamination was identified
  - Root cause was determined to be use of a catheter smaller than the recommended catheter by the manufacturer
  - Corrective actions included discontinuation of microcatheters with inner diameter smaller than 0.5 mm in accordance with recommendations
  - No adverse effects to the patient were expected

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220091]
  - Patient prescribed 0.51 GBq (13.78 mCi), received 0.16 GBq (4.32 mCi)
  - Discovered during a review of microsphere procedures, licensee incorrectly assumed this was not reportable because they revised treatment plan and WD after treatment
  - Root cause was determined to be use of a smaller than recommended catheter
  - AU stated that dose was medially satisfactory and then smaller diameter catheter was necessary to treat the patient
  - Corrective actions included providing additional training to staff

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220087]
  - Patient prescribed 0.3 GBq (8.11 mCi), received 0.11 GBq (2.97 mCi)
  - Discovered during a review of microsphere procedures, licensee incorrectly assumed this was not reportable because they revised treatment plan and WD after treatment
  - Root cause was determined to be use of a smaller than recommended catheter
  - AU stated that dose was medially satisfactory and then smaller diameter catheter was necessary to treat the patient
  - Corrective actions included providing additional training to staff

35.1000 TheraSphere™

- Y-90 TheraSphere™ underdose [220190]
  - Patient prescribed 12,000 cGy (rad), received 9,420 cGy (rad)
  - Stasis was not reached, and no apparent cause was identified
  - Au had written that 12,000 cGy (rad) was the desired dose on the WD, but the dose received from the manufacturer had a maximum expected dose of 11,000 cGy (rad)
  - If the WD had been updated with this dose, then the administration would have not tripped the ME criteria
  - Corrective actions included training to WD updates

35.1000 TheraSphere™

- Y-90 TheraSphere™ wrong site [220296]
  - Patient prescribed 1.45 GBq (39.2 mCi) to the right lobe of the liver for 14,800 cGy (rad), received 24,000 cGy (rad) to the left lobe of the liver
  - Root cause was determined to be variant anatomy
  - Patient was brought back in to treat the correct lobe of the liver

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® overdose [220280]
  - Patient prescribed 2.2 GBq (59.46 mCi), received 5.07 GBq (137 mCi)
  - NM ordered a full unit dose and mistakenly administered the full dose during the treatment
  - Dose was not verified prior to administration and WD was incorrectly filled out with received and ordered doses
  - Root cause was determined to be human error
  - Corrective actions included implementation of a new procedure

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® overdose [210492]
  - Patient prescribed 0.4 GBq (10.81 mCi) and 1.6 GBq (43.24 mCi), received 0.51 GBq (13.78 mCi) and 2.19 GBq (59.19 mCi)
  - A calculational error occurred when converting from GBq to mCi, resulting in the larger doses
  - Corrective actions included an updated WD that explicitly lists the conversion factor from GBq to mCi, and the conversion to be performed by the NMT not just the manufacturer representative
  - No adverse effects were identified or expected

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220404]
  - Patient prescribed 0.5 GBq (13.51 mCi), received between 0.386 (10.43 mCi)
  - Root cause was determined to be a clogged catheter
  - Corrective actions included implementation of a new quality management plan
  - No adverse effects are expected

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220351]
  - Patient prescribed 599.4 MBq (16.2 mCi), received 469.9 MBq (12.7 mCi)
  - Error discovered during post-treatment calculations
  - No root cause could be determined
  - No adverse effects were expected

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220231]
  - Patient prescribed 370 MBq (10 mCi), received 230.51 MBq (6.23 mCi)
  - Prior to treatment, contrast was injected and no leakage was observed
  - During the administration, the doctor noticed a small leak at the Leur lock connection
  - The Radiation Safety staff was notified and the doctor tightened the connector and continued the procedure after changing gloves
  - The remainder of the microspheres were administered without incident
  - Contaminated materials were then removed and surveyed to estimate the dose not delivered

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220231] (cont.)
  - The room was surveyed and found to have no contamination
  - Root cause was determined to be a lack of clear written instructions in the procedures
  - Corrective actions included an update to the procedures to include steps for checking the connections to the delivery system
  - No adverse effects were expected

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220189]
  - Patient prescribed 261.59 MBq (7.07 mCi), received 194.99 MBq (5.27 mCi)
  - Apparent cause was complicated patient vasculature, inhibiting flow of microspheres
  - No adverse effects were expected

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [220056]
  - Patient prescribed 3.25 GBq (87.84 mCi), received 1.55 GBq (41.89 mCi)
  - Procedure was halted due to occlusion of microspheres in delivery line
  - This treatment was the largest ever dose to date at this treatment facility
  - The vial was at maximum volume and the fluid appeared highly viscous
  - Root cause was determined to be too many microspheres in the vial to be properly agitated or a dysfunctional stop cock
  - Corrective actions included modification of procedures to split large doses into 2 separate vials
  - Patient was administered another dose to compensate, no adverse effects expected

35.1000 SIR-Spheres®

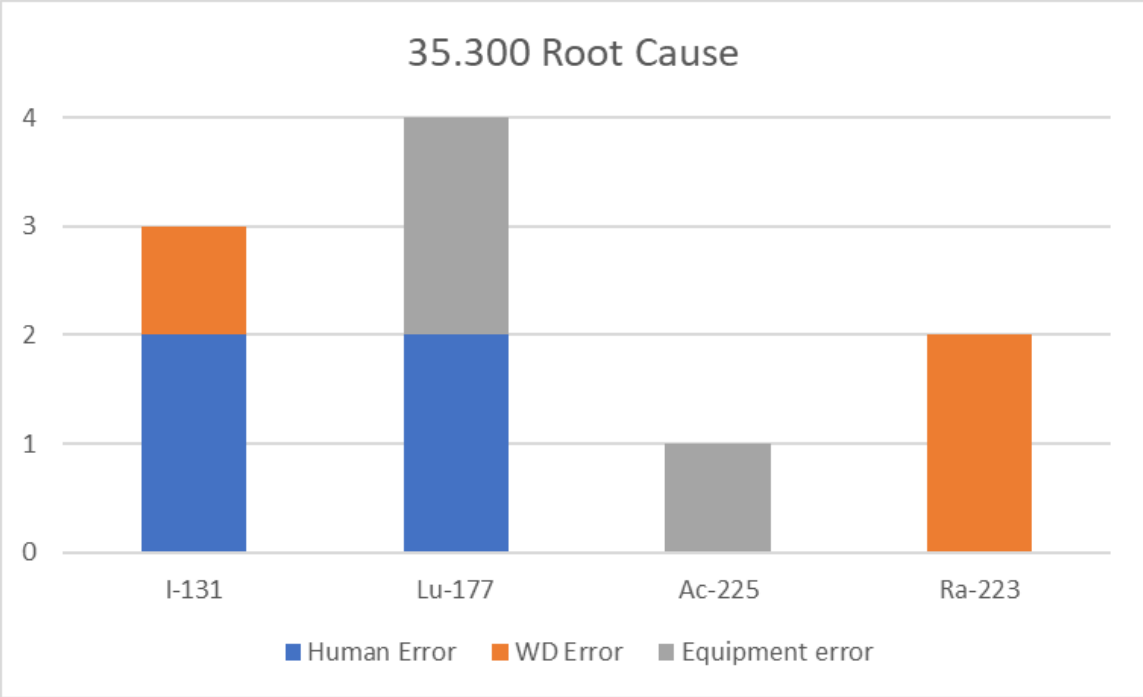
- Y-90 SIR-Spheres® underdose [210507]
  - Patient prescribed 299.7 MBq (8.1 mCi), received 233.1 MBq (6.3 mCi)
  - Procedure occurred without incident, no stasis
  - Investigations determined that a member of the staff noticed a blob of microspheres close to the vial before dose delivery
  - Manufacturer was notified and recommended gentle shaking of the vial before delivery
  - AU determined that the dose delivered was effective
  - Corrective actions included checking the vial prior to delivery and following manufacturer recommendations to shake the vial gently if accumulation is observed
  - No adverse effects were expected

35.1000 SIR-Spheres®

- Y-90 SIR-Spheres® underdose [210474]
  - Patient prescribed 185 MBq (5 mCi), received 135.79 MBq (3.67 mCi)
  - Remaining microspheres held up in delivery system
  - Investigation noted that the dose was unusually small compared to previous procedures
  - The amount of remaining microspheres was approximately the same as in previous procedures, but the smaller size of the initial dose resulted in a reportable underdose
  - Corrective actions included additional saline flushes to minimize residual microspheres and the addition of 20% more activity for low dose prescriptions (<370 MBq (10 mCi)) to account for anticipated residual microspheres
  - Additionally, the licensee implemented more frequent monitoring of hands-on personnel to identify potential contamination
  - No adverse effects were expected, and no additional dose was required

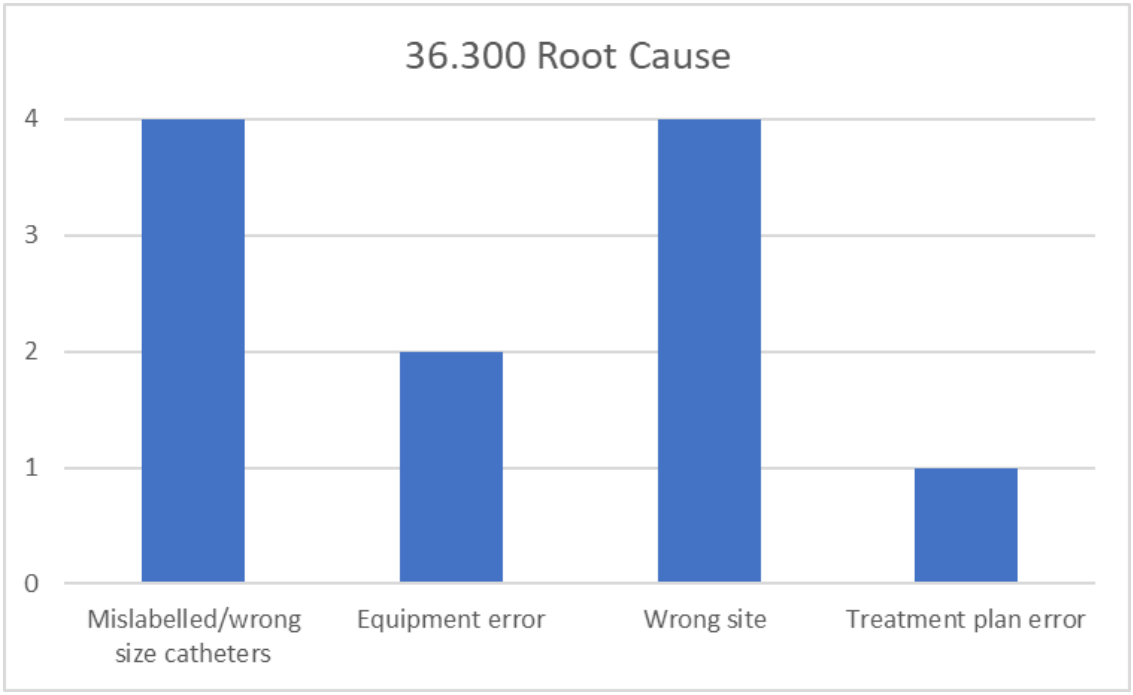
Summary

- 35.300
  - Delivered intended dose but incorrect WD
  - Full dose administration of Lu-177 but reduced dose on WD
  - Ac-225 difficulties with lead shielded syringe, resulting in leakage



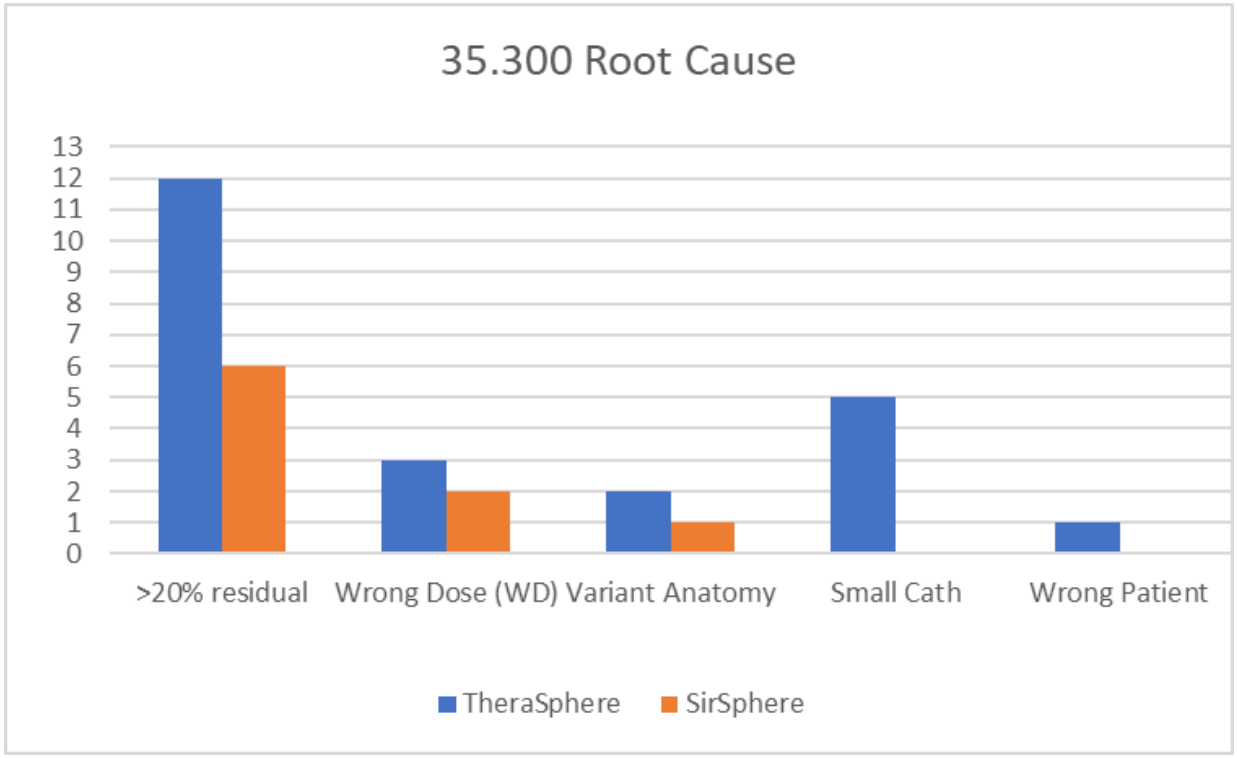
Summary

- 35.600
  - 4 misidentified lesion sites
  - Use of incorrect tube/catheter lengths
  - Multiple patients affected by single medical event, catheter/tube length problems



Summary

- 35.1000
  - Primarily Theraspheres, primarily underdoses
  - 4 events due to use of smaller than recommended catheters
  - 2 events due to malfunctioning Luer locks
  - 2 events due to unusually small doses
  - 3 of 6 overdose events were due to incorrect WD



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

Acronyms

- I-125 – Iodine-125
- I-192 –Iridium-192
- IVB – Intravascular Brachytherapy
- Lu-177 – Lutetium-177
- MBq – Mega Becquerel
- µCi - microcurie
- mCi – millicurie
- NMT – Nuclear medicine technician
- RSO – radiation safety officer
- SI units – International System of Units
- WD- Written Directive
- Y-90 – Yttrium-90

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QUESTIONS?

Abnormal Occurrence Reporting

Edward Harvey
US Nuclear Regulatory Commission
Office of Nuclear Regulatory Research

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Agenda

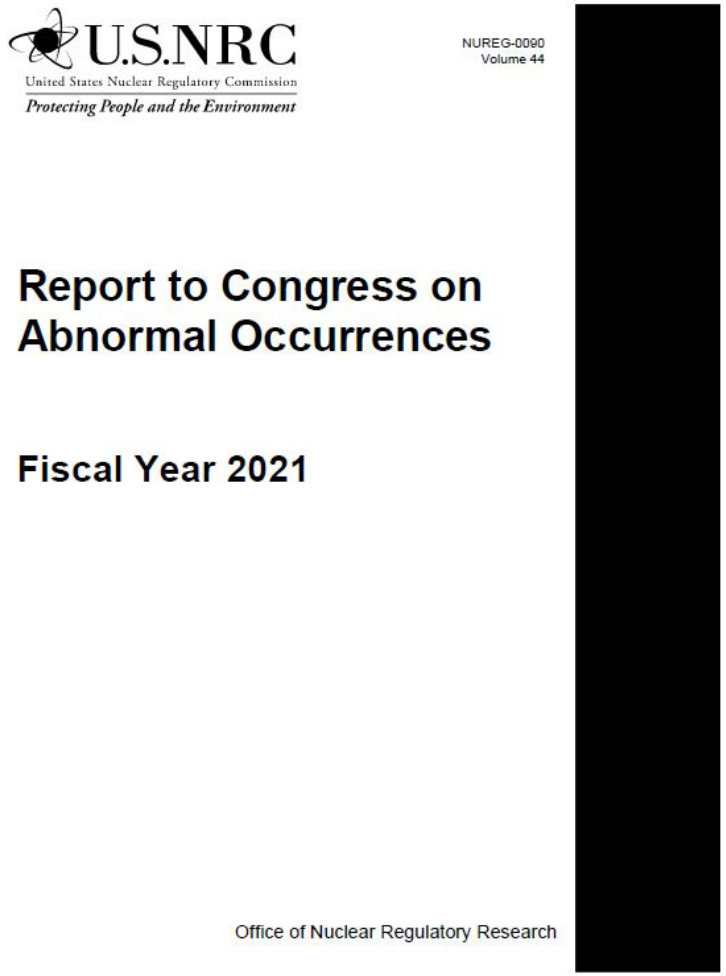
- Background
- Proposed Changes (Appendix A)
- SRM-SECY-22-0009
- Path Forward

Background

What is an Abnormal Occurrence (AO)?

AO Criteria

Annual Report to Congress (NUREG-0090)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NUREG-0090
Volume 44

Report to Congress on Abnormal Occurrences

Fiscal Year 2021

Office of Nuclear Regulatory Research

Office of Nuclear Regulatory Research

More Background

SECY-19-0088: “Evaluation of Thresholds for Reporting Abnormal Occurrences in Response to SRM-M190423” (ML19191A281)

SRM-SECY-19-0088 (ML20209A564)

SECY-22-0009: “Proposed Limited Revision to Policy Statement On Criteria for Reporting Abnormal Occurrences” (ML21217A201)

Proposed Changes

Criterion I.C.1: Proposed to add an exception to stolen, diverted, or abandoned sources

Proposed Changes

Criterion III.C.1: Proposed to remove the need for a written directive to qualify as an AO

Proposed Changes

Criterion III.C.2: Proposed to shift to a deterministic consequence-based reporting criteria (radiation induced injury)

SRM-SECY-22-0009

- Signed March 29, 2023
- Approved/disapproved proposed changes
- Directed staff to evaluate removal of Criterion III.C.2
- Directed staff to incorporate Commission comments and publish for public comment (90 days)

Path Forward

01

Staff proposed to maintain Criterion III.C.2

02

Staff will incorporate Commission comments and publish AO criteria in the Federal Register for a 90-day public comment period

03

Comments will be docketed and evaluated

04

Work toward final publication

Questions?

NRC's Medical Team Updates

Celimar Valentin-Rodriguez, PhD
Medical Radiation Safety Team Leader
Division of Materials Safety, Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards
May 15, 2023

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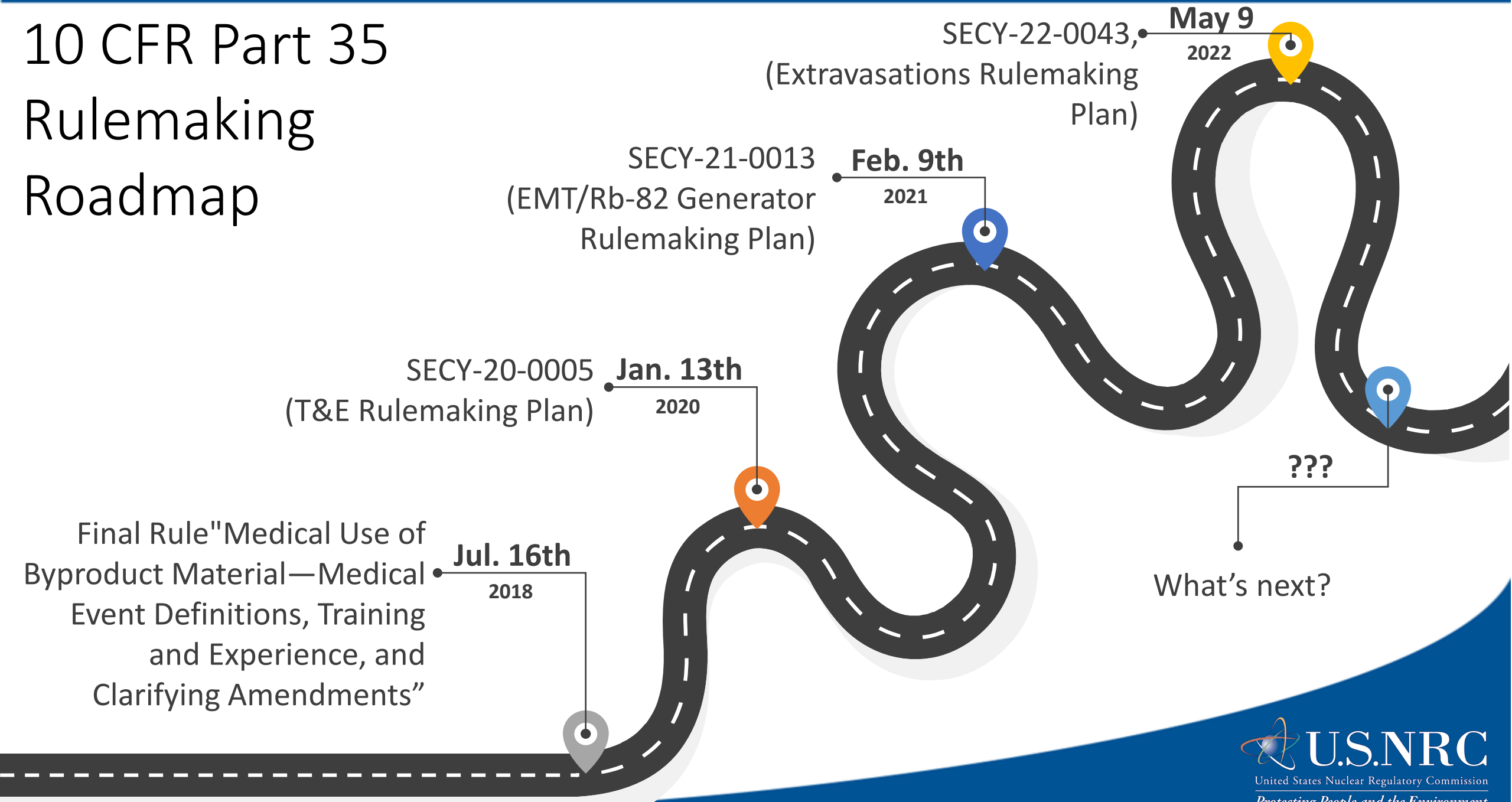
Agenda

- RULEMAKINGS
- REGULATORY GUIDANCE
- OPPORTUNITIES FOR ENGAGEMENT
- QUESTIONS

10 CFR Part 35 Rulemaking Roadmap



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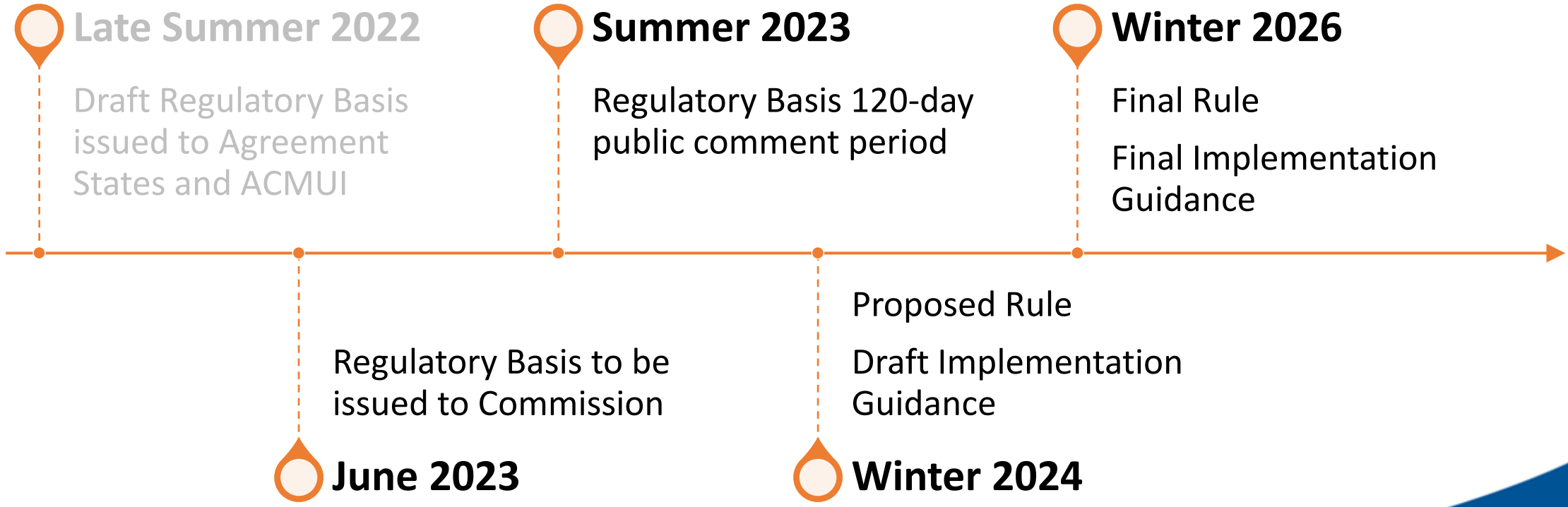
EMT/Rb-82 Generator Rulemaking



Veterinary Release

- Current guidance for veterinary release in NUREG-1556, Vol. 7, Rev. 1, Appendix D has specific criteria for NaI-131 treatment for cats.
- NRC issued a technical report for the evaluation of Exubrion Therapeutic's request to release dogs after Sn-177m colloid treatment.
- NRC and OAS established a working group to develop a rulemaking plan to codify release of animals administered radioactive material.
- Deferred to work on higher priority rulemakings.

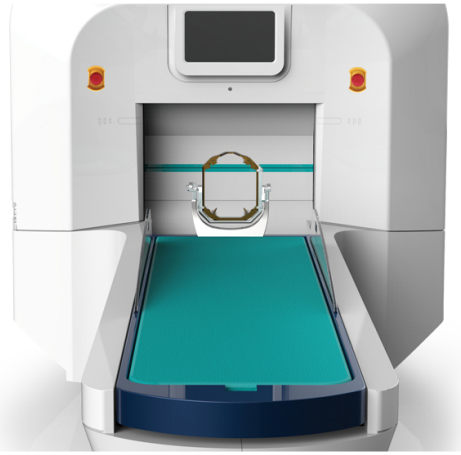
Emerging Medical Technologies

Elekta Esprit

Advanced GSR

Liberty Vision LV Y-90 Discs

Advanced Eye Applicators



Akesis Galaxy

Advanced GSRs

Regulatory Guide 8.39

- In SECY-18-0015, "Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release after Radioisotope Therapy," the NRC found that:
  - Patient release regulations are protective of public health & safety
  - Patient release guidance was outdated and could underestimate doses
  - Staff recommended a comprehensive update of RG 8.39

- The NRC decided to revise RG 8.39 in two phases.
  - Phase 1 revision was published in April 2020
  - Phase 2 revision is out for a 60-day public comment period

PHASE 1 – Update patient instructions & include generic communications info

PHASE 2 – Update dosimetric equations, methodologies, tables

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T&E Implementation Guidance

- In SRM-SECY-22-0005, the Commission maintained the status quo regarding T&E requirements for unsealed byproduct material.
- The Commission directed the staff to develop implementation guidance to clarify roles and responsibilities of individuals subject to T&E requirements.
- Working group will develop interim staff guidance by August 2024.
- ISG will be updated after EMT/Rb-82 generator rulemaking.

Reporting of Medical Events

- In SRM-SECY-22-0043, the Commission directed the staff to develop comprehensive regulatory guidance for the reporting of all medical events.
- The staff will develop an ISG to be issued concurrently with the extravasation proposed rule in 2024.
- ISG will be re-issued as final guidance following the approval of the EMT/Rb-82 generator final rule.

Household Waste from Nuclear Medicine Patients

ACMUI recommended that NRC assess the issue of detection of short-lived medical isotopes in municipal waste from nuclear medicine patients and provide some level of guidance, best practices, or additional instructions.

Sent voluntary survey to Agreement States requesting information on best practices and need for additional guidance.

Extended the comment period for the voluntary survey until end of May.

Opportunities for Engagement

- Extravasation Rulemaking Request for Information (90-day public comment period)
  - Public meeting – May 24, 2023
- RG 8.39 proposed draft revision (60-day public comment period)
- EMT/Rb-82 Generator Rulemaking Regulatory Basis – Summer 2023
- Workshop on ABR Termination and T&E Pathways – September 2023

Acronyms

- ABR – American Board of Radiology
- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- AO – Abnormal occurrence
- CFR – Code of Federal Regulations
- EMT – Emerging medical technology
- FDA – Food and Drug Administration
- ISG – Interim staff guidance
- NaI-131 – sodium iodide-131
- OAS – Organization of Agreement States
- PRM – Petition for rulemaking
- Rb-82 – rubidium-82
- RG – Regulatory guide
- RFI – Request for information
- Sn-117m – tin-177m
- SRM – Staff requirements memorandum
- T&E – Training and experience

Contact Us!

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301-415-7124

Medical Uses Licensee Toolkit | NRC Public Website

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Training and Experience for All Modalities Subcommittee Report

Hossein Jadvar, MD, PhD, MPH, MBA

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

May 15, 2023

Subcommittee Members

- Hossein Jadvar, M.D., Ph.D. (Nuclear Medicine Physician; Chair)
- Ronald D. Ennis, M.D. (Radiation Oncologist; term ended 3/17/2023)
- Richard Harvey, Ph.D. (Radiation Safety Officer)
- Darlene F. Metter, M.D. (Diagnostic Radiologist)
- Megan L. Shober (Agreement State Representative)
- Melissa C. Martin (Medical Physicist, Nuclear Medicine)
- Maryann Ayoade (NRC Staff Resource)

Subcommittee Charge

- To identify any potential impacts of ABR's request to terminate NRC recognition and other inactive boards identified during the NRC's evaluation of specialty boards and provide recommendations to mitigate any potential impacts.
- To review and evaluate the NRC's current board recognition criteria and provide any recommendations for action.

Charge 1

- To identify any potential impacts of ABR's request to terminate NRC recognition and other inactive boards identified during the NRC's evaluation of specialty boards and provide recommendations to mitigate any potential impacts.

NRC Recognized Boards
(certificate holder can request to NRC for granting AU status)

- American Board of Healthy Physics (ABHP)
- American Board of Science in Nuclear Medicine (ABSNM)
- American Board of Radiology (ABR)
- American Board of Medical Physics (ABMP)
- Canadian College of Physicists in Medicine (CCPM)
- Board of Pharmacy Specialties (BPS) [Formerly Board of Pharmaceutical Specialties]
- The American Board of Nuclear Medicine (ABNM)
- Certification Board of Nuclear Cardiology, Part of the Alliance for Physician Certification and Advancement™ Medical Specialty Boards and Certification Programs (CBNC)
- The American Osteopathic Board of Radiology (AOBR)
- The American Osteopathic Board of Nuclear Medicine (AOBNM) --- INACTIVE since March 5, 2019……no longer recognized
- Certification Board of Nuclear Endocrinology (CBNE) --- INACTIVE, no longer recognized

American Board of Radiology (ABR) Background

- Founded in 1934 as a non-for-profit organization and a member of the American Board of Medical Specialties (ABMS), one of 24 specialty certifying boards
- Certifying board for Diagnostic Radiology (DR), Interventional Radiology (IR), Medical Physics (Diagnostic, Nuclear, Therapeutic), Radiation Oncology (RO), and subspecialties (Nuclear Radiology, Neuroradiology, Pediatric Radiology)
- Mission
  - To certify that our diplomates demonstrate the requisite knowledge, skill, and understanding of their disciplines to the benefit of patients.
- Interview with Dr. Brent Wagner, ABR Executive Director (12/5/2022)

American Board of Radiology (ABR) Background

- Prior to 2005: ABR did not provide AU/AMP/RSO-E designation on board certificates
- 2005-2023: AU-E, AMP-E, & RSO-E designations was an option for candidates
- December 31, 2023: Last date for AU-E designation on certificates (DR, IR-DR, RO); RSO-E on certificates (Diagnostic MP and Nuclear MP), and AMP-E on certificates (Therapeutic MP)
- 2024 and beyond: No AU/AMP/RSO-E designation option; candidates provide relevant T&E documentation through their employers directly to NRC to add the employee to employer's license
- REASONS (https://www.youtube.com/watch?v=hkRc9JzP2oA) March 30, 2022
  - not aligned with the core ABR mission; diverts limited resources
  - ABR has never issued AU status; most radiologists are not (and do not need to be) AUs
  - ABR merely passed along documentation of T&E and direct pathway to becoming AU exists
  - AU requirement for 700h T&E in nuclear radiology is an ACGME ("residency") requirement
  - IR-DR(Forms A & B), RO (2-page verification form) need not be submitted to ABR
  - RISE questions will not be scored separately
  - Trainees and programs should continue to keep T&E documentation
  - T&E docs needed for 16-m embedded NM/DR pathway and NR fellows to sit for NR CAQ exam
  - *"ABR change is more cosmetic than substantive"*

Ramifications & Potential Issues

- Potential confusion and challenges with burden on applicants and institutions for securing AU, AMP, or RSO status for new hires
  - AU-E board certification is rapid for proof of AU eligibility; ABR may have underestimated the burden being placed on the applicants, preceptors, and program directors
  - Deceased preceptors, unwilling preceptors to sign off if >7y window (per requirement in 10 CFR 35.59) or if preceptor was not involved with applicant's T&E
  - Potential increase in time reviewing T&E documentations (NRC & Agreement States); possible delays may impact practice of medicine (AU-E could function immediately)
    - California: 4h per license amendment; ~100 AUs added per year; no time difference between ABR certification v. alternate pathway
    - Wisconsin: no apparent adverse impact on regulatory agencies based on licensing databases for 2020/2021
    - SECY-20-0005: Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35), cost-benefit analysis, 15 hrs for NRC, 11 hrs for Agreement States, and 5 hrs for licensees

Ramifications & Potential Issues (cont.)

- ~67%-95% (Avg. ~80%) of ABR certifications included AU-E; unclear what % become AUs on RAM licenses (IR estimated at 50%)
- No indications that other NRC recognized entities will follow ABR's decision
  - CBNE (dissolved and no longer recognized)
  - AOBNM (inactive since March 2019, no longer recognized, and very small even when they were active)
- Association of University Radiologists (AUR), Society of Chairs of Academic Radiology Departments (SCARD), Society of Chairs of Academic Radiation Oncology Programs (SCAROP), and Association of Program Directors in Radiology (APDR) meetings may be appropriate venues for discussions
- Potential publication of recommendations in the AUR flagship journal, Academic Radiology

Charge 2

- To review and evaluate the NRC's current board recognition criteria and provide any recommendations for action

Charge 2: *To review and evaluate the NRC's current board recognition criteria and provide any recommendations for action*

- Discussed the current NRC board recognition criteria as outlined in:
  - ML22125A247 (Evaluation of NRC-Recognized Specialty Boards)
  - ML20351A389 (Procedures for Recognizing, Monitoring, and Terminating the Certification Process of Specialty Boards)
  - ML12164A741 (Authorized User Training, Experience, and Preceptor Attestation – for uses defined under 35.300 [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396]).
  - Certification by a specialty board, coupled with recentness of training is sufficient for seeking AU status on RAM license and attestation by preceptor is unnecessary.
  - Subcommittee agreed that these documents are sufficiently comprehensive and detailed.

References

- What you need to know about the recent ABR decision related to authorized user eligibility. https://orbitcme.com/blog/what-you-need-to-know-about-the-massive-abr-decision-on-authorized-user-eligibility/
- Baldwin JA, et al. All you need to know as an authorized user. *Am J Roentgenol* 2015; 205:251-258.
- 10 CFR 35.50 – Training for radiation safety officer and associate radiation safety officer
- 10 CFR 35.51 – Training for an authorized medical physicist
- 10 CFR 35.55 – Training for an authorized nuclear pharmacist
- 10 CFR 35.59 – Recentness of training
- 10 CFR 35.190 – Training for uptake, dilution, and excretion studies
- 10 CFR 35.290 – Training for imaging and localization studies
- 10 CFR 35.390 – Training for use of unsealed byproduct material for which written directive is required
- 10 CFR 35.392 – Training for the oral administration of sodium iodide (I-131) requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- 10 CFR 35.394 – Training for the oral administration of sodium iodide (I-131) requiring a written directive in quantities greater than or equal to 1.22 gigabecquerels (33 millicuries)
- 10 CFR 35.490 – Training for use of manual brachytherapy sources
- 10 CFR 35.690 – Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

Acronyms

- AAPM – American Association of Physicists in Medicine
- ABR – American Board of Radiology
- ABNM – American Board of Nuclear Medicine
- ACGME – Accreditation Council for Graduate Medical Education
- AU-E – Authorized User-eligible
- AMP-E – Authorized Medical Physicist-eligible
- CAQ – Certificate of Added Qualification
- CAMPEP – Commission on Accreditation of Medical Physics Education Programs
- IR-DR – Interventional Radiology-Diagnostic Radiology
- MP – Medical Physicist

Acronyms (cont.)

- NM-DR – Nuclear Medicine – Diagnostic Radiology
- NR – Nuclear Radiology
- NRC – Nuclear Regulatory Commission
- RO – Radiation Oncology
- RISE – Radioisotope Safety Exam
- RSO-E – Radiation Safety Officer-eligible
- T&E – Training and Experience

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

Subcommittee on Training and Experience for All Modalities

Draft Report
Submitted on April 28, 2023

Subcommittee Members:
Hossein Jadvar, M.D., Ph.D. (Nuclear Medicine Physician; Chair)
Ronald Ennis, M.D. (Radiation Oncologist; term ended 3/17/2023)
Richard Harvey, Ph.D. (Radiation Safety Officer)
Darlene F. Metter, M.D. (Diagnostic Radiologist)
Megan L. Shober (Agreement State Representative)
Melissa C. Martin (Medical Physicist, Nuclear Medicine)

NRC Staff Resource: Maryann Ayoade

Subcommittee Charge:

The T&E Subcommittee was re-established in 2022 by Dr. Darlene Metter, Chair of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), with expanded charges to:

- Identify any potential impacts of ABR's request to terminate NRC recognition and other inactive boards identified during the staff's evaluation of specialty boards and provide recommendations to mitigate any potential impacts.
- Review and evaluate the NRC's current board recognition criteria and provide any recommendations for action.

The Subcommittee reviewed the relevant literature (see reference section) and met virtually several times to discuss the charge and propose several considerations in consultation with the NRC staff. The Subcommittee reported on the first charge above during the ACMUI meeting and the Commissioner's meeting in December 2022. The second charge was further discussed during early 2023. The Subcommittee's conclusions for both charges are included in this document.

Introduction:

The American Board of Radiology (ABR, founded in 1934 as a non-for-profit organization and a member of the 24 certifying boards within the American Board of Medical Specialties, ABMS) announced in March 2022 that the board will no longer include Authorized User-Eligible (AU-E), Radiation Safety Officer-Eligible (RSO-E), and Authorized Medical Physicist-Eligible (AMP-E) designations on their certificates for all NRC-recognized ABR certification processes (for all specialty areas) starting on January 1, 2024, for individuals seeking authorization on NRC or Agreement State radioactive materials licenses:

1. AU-E designation for Diagnostic Radiology (DR), Interventional Radiology/Diagnostic Radiology (DR/IR), and Radiation Oncology (RO) certificates;
2. RSO-E designation for Diagnostic Medical Physics and Nuclear Medical Physics certificates; and
3. AMP-E for Therapeutic Medical Physics certificates.

Prior to 2005, the ABR did not provide AU/RSO/AMP–Eligible designations on their certificates. During 2005-2023, after receiving NRC recognition, these designations were an option for candidates. The ABR provided the following reason for the decision to discontinue including these designations on the certificates (https://www.youtube.com/watch?v=hkRc9JzP2oA):

- Not aligned with the core ABR mission ("to certify that our diplomates demonstrate the requisite knowledge, skill, and understanding of their disciplines to the benefit of patients"); diverts limited resources,
- ABR has never issued AU status; most radiologists are not (and do not need to be) AUs,
- ABR merely passed along documentation of T&E and direct (alternate) pathway to becoming AU exists,
- AU requirement for 700h T&E in nuclear radiology is an ACGME ("residency") requirement,
- DR/IR (Form A - checklist related to the RC 80-h curriculum; Form B - I-131 documentation), RO (2-page verification form) need not to be submitted to ABR,
- Radioisotope Safety Exam (RISE) questions will not be scored separately,
- Trainees and programs should continue to keep T&E documentation,
- T&E documentation needed for 16-m embedded NM-DR pathway and NR fellows to sit for NR CAQ exam,
- T&E documentation needed for Radiation Oncology for AU status designation,
- "ABR change is more cosmetic than substantive".

The ABR indicated that from 2024, the candidates should provide the relevant T&E documentation through their employers directly to the NRC or Agreement States in order to add the employee to the employer's Radioactive Material (RAM) license.

<u>Subcommittee Specific Comments</u>:

<u>Charge</u>: To identify any potential impacts of ABR's request to terminate NRC recognition and other inactive boards identified during the staff's evaluation of specialty boards and provide recommendations to mitigate any potential impacts.

The subcommittee reviewed a number of relevant articles (see references), gathered data from few states, and asked the ABR's Executive Director, Dr. Brent Wagner, to

participate live with discussions and answer the subcommittee's questions. The following conclusions were reached:

1) There may be, at in least in the short term, challenges with attaining AU status since AU-E designation on certificates was a rapid proof of AU eligibility and with the ABR's decision, the burden of proof is being placed on the applicants, preceptors, and training program directors to provide relevant documentation. It is plausible that in some cases the preceptors may be deceased or unwilling to sign off T&E documentation if there is >7 years window (per requirement in 10 CFR 35.59), or if the preceptor was not initially involved with applicant's T&E.
2) Despite the concern expressed in item 1 above, the sampled environmental data indicated that, for example, in Wisconsin, only a minority of AU licenses were granted through ABR AU-E designation on board certification (majority were through the alternate pathway). The 2020-21 ABR data indicated that 67% of DR, 79% DR/IR, 97% of RO certificates had AU-E designations. The percentages for AMP-E and RSO-E were almost 100%. However, despite these high percentages of designations, it was unclear how many individuals holding AU-E designations on their certificates actually applied for and were declared AU, although it is presumed that the conversion fraction is relatively small.
3) In California, it was estimated that it takes approximately 4 hours per license amendment for documentation evaluation by the regulator and that there was no significant time difference in the evaluations of the ABR AU-E certificates and the alternate pathway. As for benchmark reference, SECY-20-0005, Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material 10 CFR Part 35 (ML19217A318) cost-benefit analysis, the time spent per applicant for documentation evaluations were 15 hours for NRC, 11 hours for Agreement Sates, and 5 hours for licensees.
4) There was no credible indication that other NRC-recognized entities will follow the ABR's decision. Of note, the following boards are either dissolved or inactive and are currently listed on the NRC-recognized specialty board certifications webpage as no longer recognized by the NRC:
    a. Certification Board of Nuclear Endocrinology
    b. American Osteopathic Board of Nuclear Medicine
5) The subcommittee suggested that further discussions may be appropriate within the annual meetings of the Association of University Radiologists (AUR), Society of Chairs of Academic Radiology Departments (SCARD), Society of Chairs of Academic Radiation Oncology Programs (SCAROP), and Association of Program Directors in Radiology (APDR).
6) The subcommittee recommends publication of the subcommittee recommendations (approved by the ACMUI) in the AUR flagship journal, Academic Radiology.

Charge: To review and evaluate the NRC's current board recognition criteria and provide any recommendations for action.

The subcommittee discussed the current NRC board recognition criteria as outlined in "NMSS Procedure MSST-70-03, Revision 2: Procedures for Recognizing, Monitoring, and Terminating the Certification Process of Specialty Boards" (ML20351A389), "2022 Evaluation of NRC-Recognized Specialty Boards" (ML22125A247), and NRC Form 313A (AUT): Authorized User Training, Experience, and Preceptor Attestation – for uses defined under 35.300 [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (ML12164A741). It was also noted and discussed that per the NRC final rule "Medical Use of Byproduct Material – Medical event definitions, Training and Experience, and Clarifying Amendments" published in the Federal Register on July 16, 2018 (83 FR 33046):

"Training and experience requirements are amended in multiple sections to remove the requirement to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC has determined that certification by a specialty board, coupled with meeting the recentness of training requirements, is sufficient to demonstrate that an individual seeking authorization on a license has met the T&E requirements and has the requisite current knowledge and, therefore, additional attestation by a preceptor is unnecessary. Individuals who are not board certified will still need to obtain a written attestation; however, the language of the attestation is modified. Additionally, residency program directors will be allowed to provide these written attestations."

It was agreed that board recognition criteria as described in these documents are sufficiently comprehensive and detailed. The Subcommittee does not recommend any changes to the NRC board recognition criteria.

References:

What you need to know about the recent ABR decision related to authorized user eligibility. https://orbitcme.com/blog/what-you-need-to-know-about-the-massive-abr-decision-on-authorized-user-eligibility/

Baldwin JA, et al. All you need to know as an authorized user. Am J Roentgenol 2015; 205:251-258.

10 CFR 35.50 – Training for radiation safety officer and associate radiation safety officer.
10 CFR 35.51 – Training for an authorized medical physicist
10 CFR 35.55 – Training for an authorized nuclear pharmacist
10 CFR 35.59 – Recentness of training
10 CFR 35.190 – Training for uptake, dilution, and excretion studies
10 CFR 35.290 – Training for imaging and localization studies

10 CFR 35.390 – Training for use of unsealed byproduct material for which a written directive is required
10 CFR 35.392 – Training for the oral administration of sodium iodide (I-131) requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
10 CFR 35.394 – Training for the oral administration of sodium iodide (I-131) requiring a written directive in quantities greater than or equal to 1.22 gigabecquerels (33 millicuries)
10 CFR 35.490 – Training for use of manual brachytherapy sources
10 CFR 35.690 – Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

Respectfully Submitted on April 28, 2023
Training and Experience for All Modalities Subcommittee
Advisory Committee on the Medical Uses of Isotopes (ACMUI)
U.S. Nuclear Regulatory Commission (NRC)

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

Update on the Reporting Nuclear Medicine Injection Extravasations as Medical Events Rulemaking

Irene Wu

May 15, 2023

Agenda

- Background
- Information Request and Preliminary Proposed Rule Language
- Next Steps
- Questions

Medical Event Reporting Requirements

- In a 1980 final rule (45 FR 31701), the Commission did not require licensees to report extravasations to the NRC.
- Radiopharmaceutical extravasations are currently not required to be reported by the Commission.

NRC Staff Evaluation

- Beginning in January 2020, staff conducted an independent evaluation of whether extravasations should be reported as medical events.
- Stakeholder engagement included:
  - Public meeting in December 2020 (ML21005A436)
  - ACMUI meeting in September 2021 (ML21267A021)

Petition for Rulemaking and Rulemaking Plan

- In May 2020, PRM-35-22 requested the NRC to revise its regulations to require medical event reporting of extravasations.
- In May 2022, NRC staff provided a rulemaking plan to the Commission (SECY-22-0043).
- In December 2022, the Commission approved staff's recommendation with changes (SRM-SECY-22-0043).

Information Request

- The information request was published in the *Federal Register* on April 19, 2023 (88 FR 24130).
- The deadline for comments is July 18, 2023.
- The notice made the preliminary proposed rule language for the rulemaking available and posed questions to obtain input from stakeholders.

Preliminary Proposed Rule Language

The preliminary proposed rule language does not represent a final NRC staff position, nor has it been reviewed by the Commission. Therefore, the preliminary proposed rule language may undergo revision during the rulemaking process.

Preliminary Proposed Rule Language

§ 35.2 Definitions.

- ***Extravasation*** means the leakage of a radiopharmaceutical from the blood vessel into the surrounding tissue.

- ***Medical attention*** means any techniques used to reduce the chance, severity, or symptoms of a suspected radiation injury.

- ***Suspected radiation injury*** means a potential or observable deterministic health effect to the area around an injection site that can be attributed to radiation.

Information Request Questions

Definitions

1. What term should the NRC use (e.g., extravasation, infiltration) when describing the leakage of radiopharmaceuticals from a blood vessel or artery into the surrounding tissue?
2. What criteria should the NRC use to define “suspected radiation injury”?
3. What techniques or methods should be included in the definition of “medical attention”?

Preliminary Proposed Rule Language

§ 35.42 Procedures for evaluating and reporting extravasations.

(a) For any administration in which an extravasation can occur, the licensee must develop, implement, and maintain written procedures to provide high confidence that an extravasation that requires medical attention for a suspected radiation injury will be detected and reported in a timely manner and in accordance with § 35.3045.

(b) The written procedures required by paragraph (a) of this section must address how the licensee determines that an extravasation meets the criteria in § 35.3045(a)(3) for a medical event.

(c) A licensee must retain a copy of the procedures required under paragraph (a) in accordance with § 35.2042.

Preliminary Proposed Rule Language

§ 35.2042 Records for procedures for evaluating and reporting extravasations.

A licensee must retain a copy of the procedures required by § 35.42(a) for the duration of the license.

Preliminary Proposed Rule Language

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which –

(1) * * *

(2) * * *

(3) The administration of byproduct material results in an extravasation that requires medical attention for a suspected radiation injury.

Information Request Questions

Procedures

4. What steps could the licensee take to minimize the chance of a radiopharmaceutical extravasation occurring?
5. What steps should the licensee take when an extravasation is suspected or discovered?
6. What techniques, technologies, or procedures (e.g., post-treatment imaging, visual observation, patient feedback) should be used to help identify an extravasation during or immediately after a radiopharmaceutical injection?

Information Request Questions

7. What techniques, technologies, or procedures (e.g., post-treatment imaging, survey measurement) should be used to better characterize an extravasation after radiopharmaceutical treatment?
8. What information should licensees provide to nuclear medicine patients on how to identify an extravasation and how to follow up with their physician if they suspect a radiation injury?
9. When should a reportable extravasation be counted as “discovered” for the purposes of notification (e.g., when medical attention is administered, when the physician identifies that the injury is from radiation)?

Information Request Questions

10. The NRC requires that licensees notify the referring physician and the individual who is the subject of a medical event no later than 24 hours after discovery of the medical event. When should licensees be required to provide notification of an extravasation medical event to the referring physician and the individual?
11. Who (e.g., patient's primary physician, authorized user, nuclear medicine technician) should be able to identify an extravasation that could result in a "suspected radiation injury"?
12. What topics should the NRC include in guidance to assist licensees to accurately identify, characterize, and report extravasation events in a timely manner?

Information Request Questions

Healthcare Inequities

13. What regulatory actions could help ensure that extravasations in patients affected by healthcare inequities are accurately assessed and reported?
14. Are vascular access tools and other technologies (e.g., ultrasound guided vein finders) likely to reduce the potential for an extravasation in all patients, particularly in patients of color?

Methods for Submitting Comments

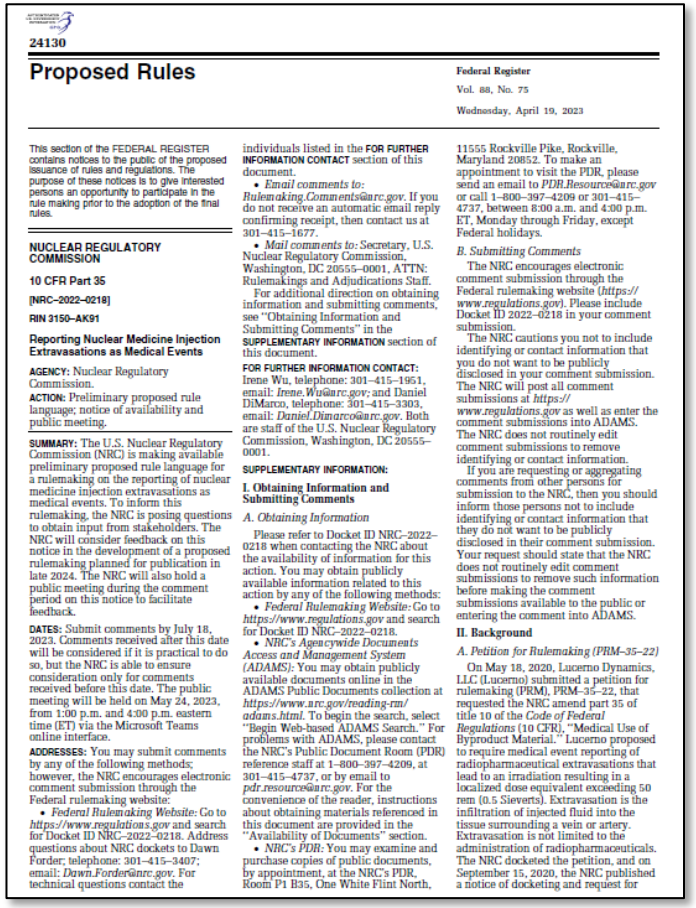
- **Regulations.gov**: comment form
  Docket ID NRC-2022-0218

  or

- **Email**: Rulemaking.Comments@nrc.gov

  or

- **Mail**: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001
  ATTN: Rulemakings and Adjudications Staff



24130

Proposed Rules

Federal Register
Vol. 88, No. 75
Wednesday, April 19, 2023

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[NRC–2022–0218]

RIN 3150–AK91

Reporting Nuclear Medicine Injection Extravasations as Medical Events

AGENCY: Nuclear Regulatory Commission.

ACTION: Preliminary proposed rule language; notice of availability and public meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is making available preliminary proposed rule language for a rulemaking on the reporting of nuclear medicine injection extravasations as medical events. To inform this rulemaking, the NRC is posing questions to obtain input from stakeholders. The NRC will consider feedback on this notice in the development of a proposed rulemaking planned for publication in late 2024. The NRC will also hold a public meeting during the comment period on this notice to facilitate feedback.

DATES: Submit comments by July 18, 2023. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received before this date. The public meeting will be held on May 24, 2023, from 1:00 p.m. and 4:00 p.m. eastern time (ET) via the Microsoft Teams online interface.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0218. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov*. For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov*. If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Irene Wu, telephone: 301–415–1951, email: *Irene.Wu@nrc.gov*; and Daniel DiMarco, telephone: 301–415–3303, email: *Daniel.Dimarco@nrc.gov*. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2022–0218 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0218.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html*. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *pdr.resource@nrc.gov*. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. ET, Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID 2022–0218 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

A. Petition for Rulemaking (PRM–35–22)

On May 18, 2020, Lucerno Dynamics, LLC (Lucerno) submitted a petition for rulemaking (PRM), PRM–35–22, that requested the NRC amend part 35 of title 10 of the *Code of Federal Regulations* (10 CFR), "Medical Use of Byproduct Material." Lucerno proposed to require medical event reporting of radiopharmaceutical extravasations that lead to an irradiation resulting in a localized dose equivalent exceeding 50 rem (0.5 Sieverts). Extravasation is the infiltration of injected fluid into the tissue surrounding a vein or artery. Extravasation is not limited to the administration of radiopharmaceuticals. The NRC docketed the petition, and on September 15, 2020, the NRC published a notice of docketing and request for

Next Steps

- Public comment period ends: July 18, 2023
- Proposed rule to the Commission: August 2024 (estimated)
- Proposed rule publication: December 2024 (estimated)

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

Questions

Contact Information and Resources

Irene Wu, Rulemaking Project Manager
Irene.Wu@nrc.gov; (301) 415-1951

Daniel DiMarco, Technical Lead
Daniel.Dimarco@nrc.gov; (301) 415-3303

Extravasations Rulemaking Website
NRC Rulemaking Process Website

Acronyms

ACMUI	Advisory Committee on the Medical Uses of Isotopes
FR	*Federal Register*
NRC	U.S. Nuclear Regulatory Commission
PRM	petition for rulemaking
SRM	staff requirements memorandum

U.S.NRC
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Protecting People and the Environment

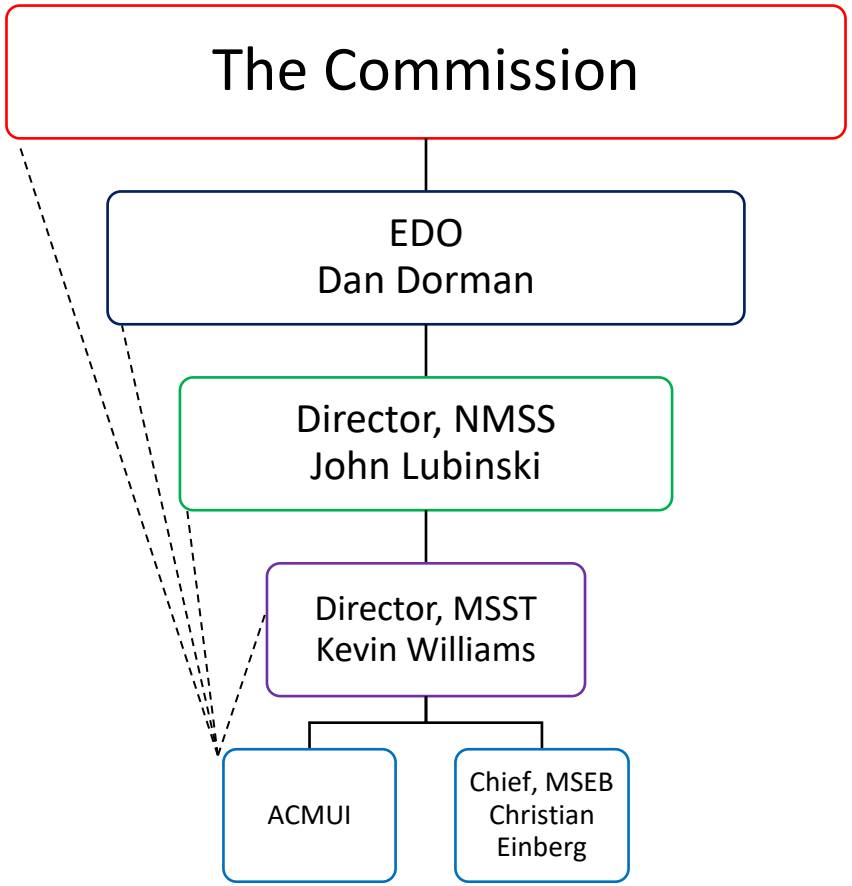
ACMUI Reporting Structure

Celimar Valentin-Rodriguez
Medical Radiation Safety Team
May 15, 2023

Outline

- Current Reporting Structure
- Annual Review
- Meetings
- Discussion

Current Reporting Structure



Annual Review

- In September 2012, the ACMUI recommended to have an annual review of reporting structure.

Meetings

- Two meetings each year
- April/May
- October/November

- Approximately 2-3 teleconferences (as needed)

ACMUI Discussion

Points of Contact

- Kevin Williams – MSST Director
- Kevin.Williams@nrc.gov

- Christian Einberg – Designated Federal Officer (DFO), Chief, MSEB
- Christian.Einberg@nrc.gov

- Lillian Armstead – ACMUI Coordinator (incoming)

Acronyms

- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- DFO – Designated Federal Officer
- EDO – Executive Director for Operations
- MSST – Division of Materials Safety, Security, States, and Tribal Programs
- MSEB – Medical Safety and Events Assessment Branch
- NMSS – Office of Nuclear Material Safety and Safeguards

Decommissioning Financial Assurance Subcommittee

Presented by Richard Harvey, Subcommittee Chair

Advisory Committee on the Medical Uses of Isotopes

May 15, 2023

U.S.NRC

United States Nuclear Regulatory Commission

Protecting People and the Environment

Financial Disclosures

- None

Subcommittee Members

- Rebecca Allen (Healthcare administrator)
- Richard Harvey, PhD (Radiation Safety Officer, Chair)
- Hossein Jadvar, MD, PhD (Nuclear Medicine Physician)
- Josh Mailman (Patients Rights Advocate)
- Melissa Martin (Medical Physicist, Nuclear Medicine)
- Megan Shober (Agreement State Representative)

- NRC Staff Resource: Cindy Flannery

Subcommittee Charge

- To review and comment on the draft proposed rule for the rulemaking for Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials.

Background

- The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations for decommissioning financial assurance for sealed and unsealed radioactive materials. The rulemaking would revise NRC's decommissioning funding requirements for radioactive material based on the relative risk to public health and safety from different radioisotopes, including naturally occurring and accelerator-produced radioactive material. The potentially affected licensees are those authorized to possess radioactive material licenses.

Proposed Rule Changes

- Language in 10 CFR 30.35, Financial assurance and recordkeeping for decommissioning will remain unchanged
- Values in Appendix B to Part 30—Quantities of Licensing Material Requiring Labeling will be updated
- Values in Appendix B will be updated to those of Appendix C of 10 CFR Part 20 for radionuclides with half-lives greater than 120 days
- No significant impact to licensees with germanium-68/gallium-68 generators
- Benefits
  - Provide relief for previously unlisted radionuclides
  - No expected negative impact to licensees

Recommendations

- The ACMUI subcommittee on the Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials Draft Proposed Rule recommends that the proposed rule with the changes to the table in Appendix B to Part 30 be accepted as proposed.

Acronyms

- ACMUI – Advisory Committee on the Medical Use of Isotopes
- CFR – Code of Federal Regulations
- DFA – Decommissioning Financial Assurance
- NRC – United States Nuclear Regulatory Commission

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

Subcommittee on the Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials Draft Proposed Rule

Draft Report
Submitted on April 28, 2023

Subcommittee Members:
Rebecca Allen (Healthcare Administrator)
Richard Harvey, PhD (Radiation Safety Officer; Chair)
Hossein Jadvar, MD, PhD (Nuclear Medicine Physician)
Josh Mailman (Patients' Rights Advocate)
Melissa C. Martin (Medical Physicist, Nuclear Medicine)
Megan L. Shober (Agreement State Representative)

NRC Staff Resource: Cindy Flannery

Subcommittee Charge: The subcommittee on the Decommissioning Financial Assurance (DFA) for Sealed and Unsealed Radioactive Materials Draft Proposed Rule was established by Dr. Darlene Metter at the Fall meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) meeting on December 5, 2022. The subcommittee was charged to review and comment on the draft proposed rule for the Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials rulemaking.

Background: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations for decommissioning financial assurance for sealed and unsealed radioactive materials. The rulemaking would revise NRC's decommissioning funding requirements for radioactive material based on the relative risk to public health and safety from different radioisotopes, including naturally occurring and accelerator-produced radioactive material. The potentially affected licensees are those authorized to possess radioactive material licenses.

Discussion: The language in the regulations in 10 CFR 30.35, Financial assurance and recordkeeping for decommissioning, will remain unchanged but the table in Appendix B to Part 30—Quantities of Licensing Material Requiring Labeling will have updated values for the radionuclides listed. The current values in the table in Appendix B to Part 30 will be updated to those of Appendix C to Part 20—Quantities of Licensed Material Requiring Labeling for radionuclides with a half-life greater than 120 days. These new values will provide relief to licensees and values for some previously unlisted radionuclides. The proposed changes will be a benefit to licensees and are not expected to negatively impact the practice of medicine.

In addition, the ACMUI report regarding Germanium-68 (Ge-68) Decommissioning Funding Plan (DFP) Final Report from August 12, 2015 was reviewed and proposed values are not anticipated to be a significant factor in the practice of medicine using these generators.

Subcommittee Recommendations: The ACMUI subcommittee on the Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials Draft Proposed Rule recommends that the proposed rule with the changes to the table in Appendix B to Part 30 be accepted as proposed.

References:

1. Draft Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials Proposed Rule **[**NRC-2017-0031] - RIN 3150-AK52

2. Germanium-68 (Ge-68) Decommissioning Funding Plan (DFP) Final Report by the ACMUI dated August 12, 2015

Respectfully submitted, April 28, 2023
Subcommittee on the Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials Draft Proposed Rule
Advisory Committee on the Medical Uses of Isotopes (ACMUI)
U.S. Nuclear Regulatory Commission (NRC)

OPEN FORUM

(No Handout)

September 2023

Highlights for September

MON	TUE	WED	THU	FRI	SAT	SUN
				1	2	3
4 *Labor Day*	5	6	7	8	9	10
11 Tentative Date #1	12 Tentative Date #1	13	14	15 *Rosh Hashanah*	16 *Rosh Hashanah*	17 *Rosh Hashanah*
18	19	20	21	22	23	24 *Yom Kippur*
25 *Yom Kippur*	26	27	28	29 *Sukkot*	30 *Sukkot*	

October 2023

Highlights for October

ASTRO	Oct.1-4

MON	TUE	WED	THU	FRI	SAT	SUN
						1 ASTRO Annual Meeting *Sukkot*
2 ASTRO Annual Meeting *Sukkot*	3 ASTRO Annual Meeting *Sukkot*	4 ASTRO Annual Meeting *Sukkot*	5 *Sukkot*	6 *Sukkot* *Shemini Atzeret*	7 *Simchat Torah*	8 *Simchat Torah*
9 *Columbus Day*	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

November 2023

Highlights for November

RSNA	Nov. 26-30

MON	TUE	WED	THU	FRI	SAT	SUN
		1	2	3	4	5
		Tentative Date #2	Tentative Date #2			
6	7	8	9	10	11	12
				Veteran's Day		
13	14	15	16	17	18	19
Tentative Date #3	Tentative Date #3	Tentative Date #4	Tentative Date #4			
20	21	22	23	24	25	26
			Thanksgiving			RSNA Annual Meeting
27	28	29	30			
RSNA Annual Meeting	RSNA Annual Meeting	RSNA Annual Meeting	RSNA Annual Meeting			

December 2023

Highlights for December

MON	TUE	WED	THU	FRI	SAT	SUN
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25 *Christmas*	26	27	28	29	30	31