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Extravasation: A Historical Perspective

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NRC Perspective

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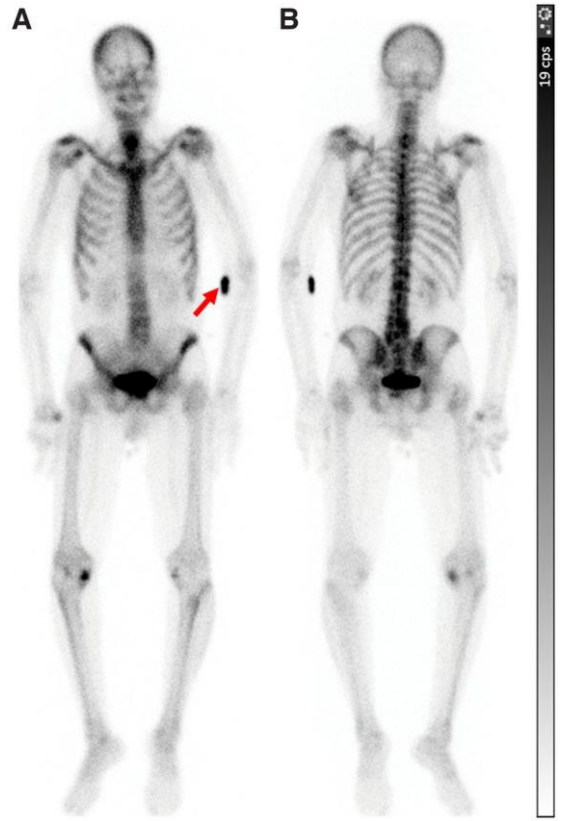
Status of Extravasations and NRC Medical Event Reporting

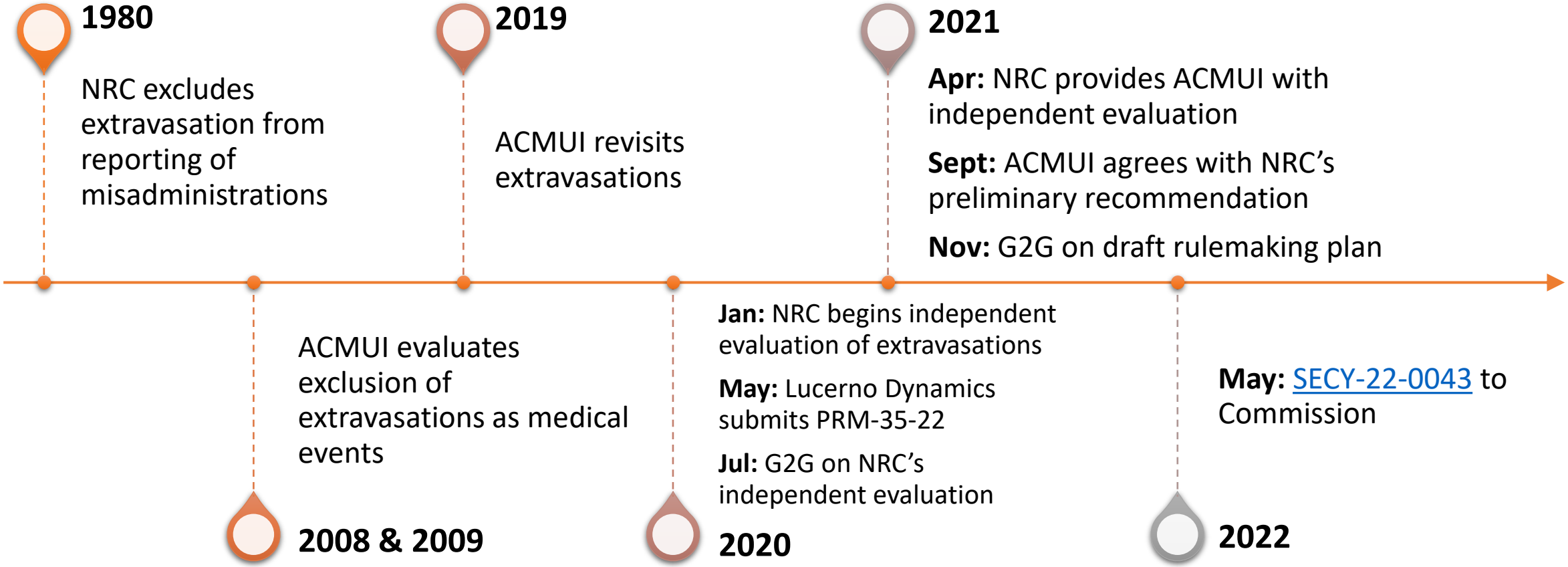
Extravasations are currently *excluded from NRC's medical event reporting*.

Extravasations are not considered wrong route of administration or wrong treatment site.



Parihar et al., JNM (2023) 64:3
https://doi.org/10.2967/jnumed.122.264994

Reporting Extravasations as Medical Events



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Misadministration Reporting Requirements, Final Rule (45 FR 31701)

- The NRC required:
  - Recordkeeping of all misadministrations of radioactive material
  - Reporting of all therapeutic misadministrations
  - Reporting of all diagnostic misadministrations on a quarterly basis

- The NRC indicated that the Commission did not consider extravasation to be misadministrations because extravasation:
  - Frequently occurs in otherwise normal intravenous or intraarterial injections
  - Is virtually impossible to avoid

Petition for Rulemaking

- 2019
  - The NRC and ACMUI received a request during the ACMUI Spring 2019 Meeting to revisit the NRC's policy that excludes extravasations from medical event reporting.
- 2020
  - The NRC receives PRM-35-22, which requests that the NRC amend 10 CFR Part 35 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).

NRC's Independent Evaluation

Whether extravasation merits regulation considering the objectives of the NRC's medical use policy statement

Whether the dose consequence from extravasation is significant enough to merit reporting

Whether extravasation can be prevented with technology

1980 2008 2009 2019 2020 2021 2022

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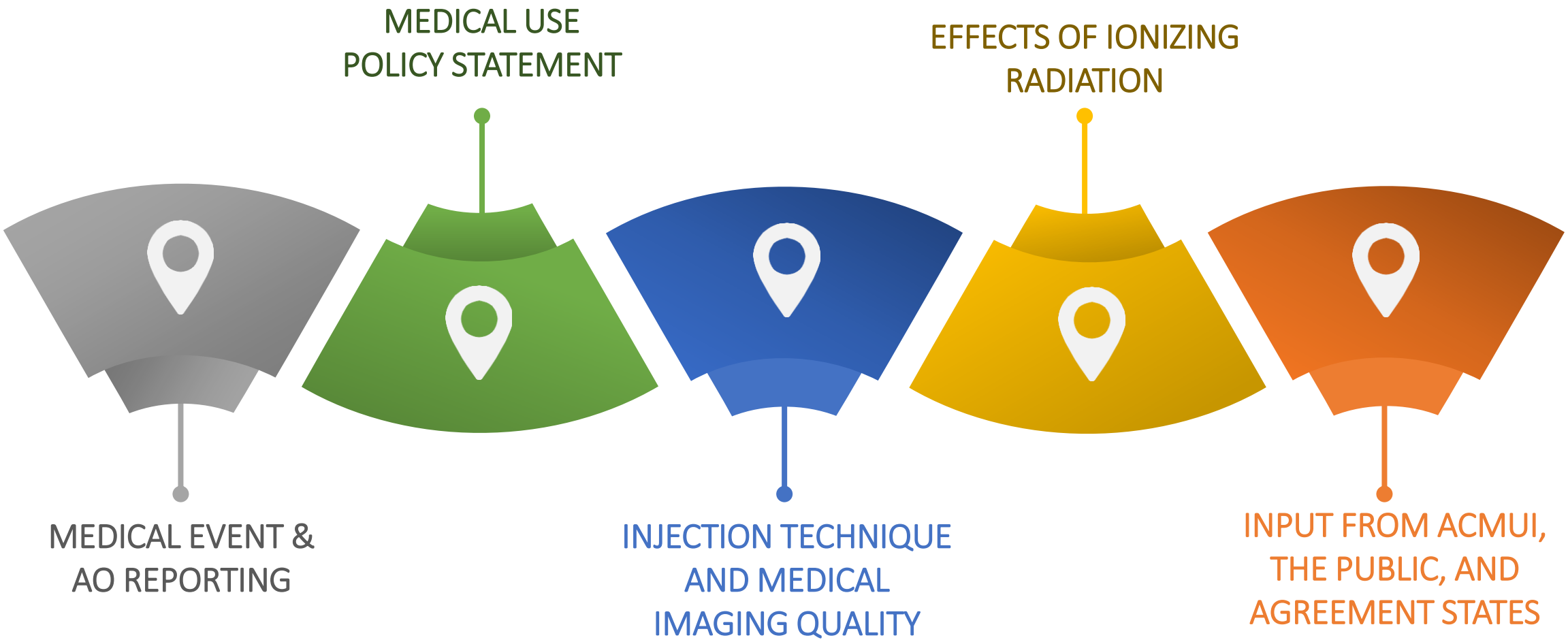
NRC's Independent Evaluation



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NRC's Independent Evaluation

OPTION 1

NO ACTION

- Align with stakeholder views regarding practice of medicine.
- Extravasation that result in patient harm would not be reported.

OPTION 2

50-REM DOSE THRESHOLD

- Consistent with existing ME reporting.
- Potential injection quality improvements.
- Increased regulatory burden if monitoring required.

OPTION 3

ADMINISTRATION SITE

- Apply to procedures requiring a WD.
- Similar to existing ME criteria.
- Require determination of expected dose to administration site and capture in WD.

OPTION 4

MEDICAL ATTENTION

- Capture diagnostic & therapeutic administrations
- No monitoring
- Rely on physician's assessment of radiological harm

OPTION 5

SIGNIFICANT DOSE

- Apply 10 Gy dose threshold similar to AOs
- No monitoring
- Require dosimetry to confirm dose

OPTION 6

PERMANENT FUNCTIONAL DAMAGE

- No reliance on dosimetry or dose threshold
- Least regulatory burden
- Responsive to ACMUI recommendation on patient intervention

1980 2008 2009 2019 2020 2021 2022

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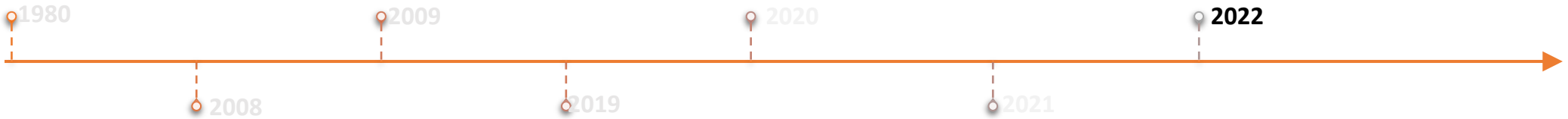
SECY-22-0043

- Submitted to the Commission on **May 9, 2022**, a rulemaking plan to disposition PRM-35-22.
- Proposed to the Commission 3 of the 6 rulemaking options discussed in the evaluation (other options in enclosure to rulemaking plan).
- Recommended reporting of ***extravasation events that require medical attention for suspected radiation injury***.

Improved Safety for Patients ✓ Increased Regulatory Effectiveness ✓ Future Regulatory Benefit



SRM-SECY-22-0043

- On **December 12, 2022**, the Commission issued SRM-SECY-22-0043.
  - Approved amending 10 CFR Part 35 requirements to include reporting of nuclear medicine injection ***extravasations that require medical attention for suspected radiation injury***.
  - Included additional actions:

01

Can we **reduce reliance on patient reporting?**

02

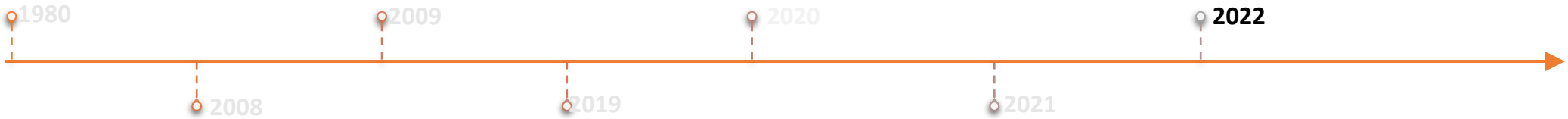
Should we require licensees to have **procedures to detect and report extravasations?**

03

Can we **accelerate the rulemaking schedule without shortening public comment periods?**

04

Develop regulatory guidance for all medical events, not only extravasation events.



Rulemaking Schedule

2022

Dec: Commission issues SRM-SECY-22-0043

2023

Apr 19: NRC issues RFI & preliminary proposed rule language

(90-day comment period + 45-day extension)

Comments due September 1, 2023

2024

Aug: Proposed rule and draft implementation guidance to be issued to Commission

2026

Mar: Final rule and implementation guidance to be issued to Commission

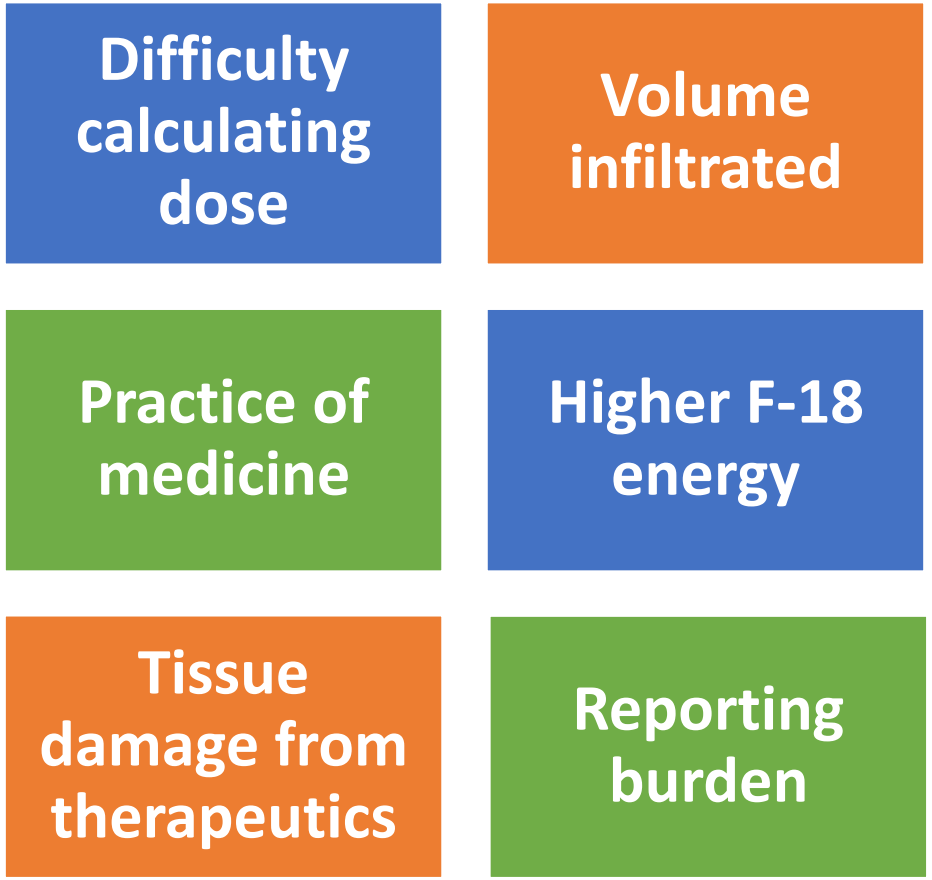
ACMUI Perspective

Megan Shober

ACMUI Agreement State Representative

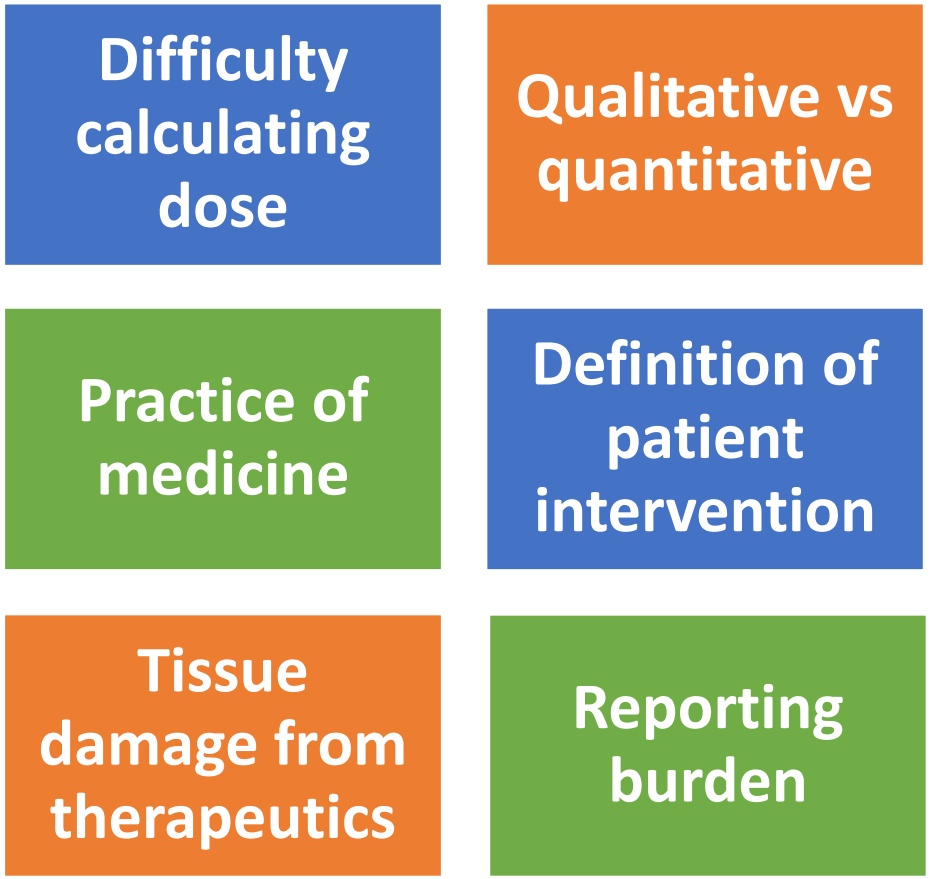
ACMUI's Evaluation (2008-2009)

- Reconsidered infiltration in light of NRC assumption of authority for accelerator-produced radioactive material.
- Passed a motion that infiltrations not be reported as medical events at this time.



ACMUI's Evaluation (2019)

- Reconsidered NRC's exemption of infiltrations and extravasations from medical event reporting based on a request made during the ACMUI Spring 2019 Meeting.
- Subcommittee report approved at Fall 2019 meeting.



ACMUI Recommendations (2019)

1. Extravasation is a practice of medicine issue that doesn't need to be regulated by NRC.
2. Under future Part 35 rulemakings, extravasations be considered a type of passive "patient intervention"…and should be captured in the NRC's definition of patient intervention in 10 CFR 35.2.
3. There is no evidence at this time to recommend considering extravasation at the injection site to be a medical event. Extravasations that lead to "unintended permanent function damage" should be reportable as a Medical Event under 10 CFR 35.3045(b).

ACMUI's Evaluation (2019)

- Dissenting opinion from one member of the Subcommittee:

Expressed concern with the existing 1980 exclusion of extravasation events from ME status. Only rare gross discrepancies in delivered dose or tissue exposure would be reportable, and those rare instances should be reported just as any other misadministration of such magnitude would be reported as MEs.

ACMUI Evaluation (2021)

- Reviewed the NRC Staff's options paper, "Preliminary Evaluation of Radiopharmaceutical Extravasation and Medical Event Reporting," dated April 2021.
- Subcommittee report approved by full ACMUI committee on September 2, 2021.
- Focused on three areas:
  - whether extravasation merits regulation considering the objectives of the NRC's medical use policy statement,
  - whether the dose consequence from extravasation is significant enough to merit reporting; and
  - whether extravasation can be prevented with technology.

ACMUI Recommendations (2021)

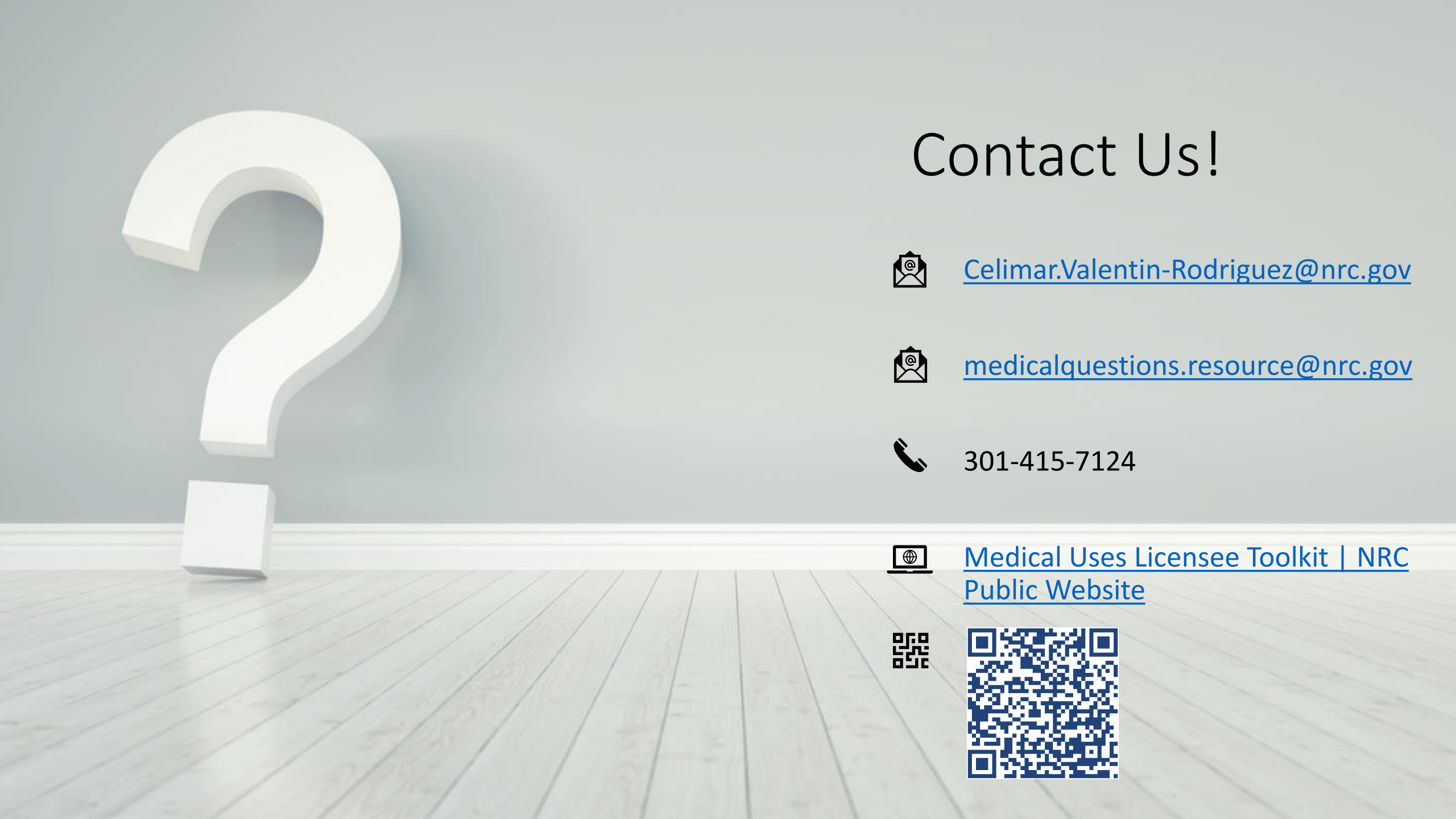
- Supported Option 4, Reporting cases that require medical attention.
  - To provide NRC with information on the types of radiation injuries caused by extravasation, and the frequency of such injuries.
  - To capture extravasation events that could result in patient harm so that they can be further evaluated for meeting the abnormal occurrence criteria.

ACMUI Conclusions (2021)

- Leverage licensees' medical quality improvement programs.
- Address concern about regulatory burden of reporting with no additional benefit to patient safety.
- Consider uncertainties about consequences of extravasation for alpha-emitting radiopharmaceuticals.

Acronyms

- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- AO – Abnormal occurrence
- Gy – Gray
- JNM – Journal of Nuclear Medicine
- PRM – Petition for rulemaking
- RFI – Request for information
- SRM – Staff requirements memorandum
- WD – Written directive



Contact Us!

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