ACMUI Update

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Advisory Committee on the Medical Uses of Isotopes (ACMUI)

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Outline

- Background
- 2019 reports
- Three medical topics
“The Committee provides advice, as requested by the Director...on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy.”
Membership

- Physicians (5)
- Medical Physicists (2)
- Radiopharmacist
- Health Care Administrator
- Patients’ Rights Advocate
- FDA Representative
- Agreement State Representative
ACMUI Meetings

• ~Five meetings per year
  – In-person (spring and fall)
  – Teleconferences
• Open to the public
• Transcribed
Subcommittees

• ACMUI members are appointed to subcommittees for special topics.
  – Rulemaking  – Medical policy
  – New technology  – ACMUI organization

• Reports are discussed in public meetings.
2019 Subcommittees

- Training and experience (10 CFR 35.390)
- 10 CFR 35.1000 licensing guidance
  - Y-90 microspheres
  - Germanium-gallium generators
  - Other draft guidance (2)
- ACMUI Institutional Memory

https://www.nrc.gov/reading-rm/doc-collections/acmui/
2019 Subcommittees

- Medical event reporting
- **Regulatory Guide 8.39**
- NRC policy on extravasation
- ACMUI Bylaws
Authorized User
Training and Experience (T&E)

• September 2018: Subcommittee advised NRC staff on questions for Federal Register notice (published in October).
• February 2019: Subcommittee submitted final T&E report.
  – No evidence of potential AU shortage
  – Did not support limited-scope AU pathway
  – Did support competency assessment (exam) for AUs with periodic re-assessment
Medical Event Reporting

• “Frequently, narrative is inadequate for an ACMUI reviewer to understand an event, its cause and contributing factors and the adequacy of the corrective action.”

• “In 23% of medical events from FY 2017-8 either no cause or no corrective action was indicated in NMED report.”
Medical Event Reporting

- Root cause and corrective actions
- Pick lists vs narrative fields
- Timeliness of record completion and closure

- Subcommittee report will be discussed at September ACMUII meeting.
NRC Extravasation Policy

• Published on May 14, 1980
  – Rulemaking on misadministrations

• What else happened that week?
  – Sports
  – Entertainment
  – Nature
What is extravasation?

- Injecting fluid into tissue surrounding a vein or artery
- Must be cleared by the lymph system

Dose is delivered, but more slowly
NRC Extravasation Policy

• “Extravasation frequently occurs in otherwise normal intravenous or intraarterial injections.”

• “It is virtually impossible to avoid. Therefore, the Commission does not consider extravasation to be a misadministration.”
NRC Extravasation Policy

• With extravasation, tissue doses can and do exceed 50 rem to the injection site.

• Is there a threshold where extravasation should be reported?

• Subcommittee report will be discussed at September ACMUI meeting.
Questions?

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Abbreviations

• ACMUI: Advisory Committee on the Medical Uses of Isotopes
• AU: Authorized User
• CFR: Code of Federal Regulation
• FDA: United States Food and Drug Administration
• NMED: Nuclear Material Events Database
• NRC: Nuclear Regulatory Commission