

# ACMUI Update

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Advisory Committee on the Medical Uses of Isotopes (ACMUI)

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# Outline

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- Background
- 2019 reports
- Three medical topics

# Charter

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“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

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

# ACMUI Meetings

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

# Subcommittees

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- 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  - Other draft guidance (2)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

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- Medical event reporting
- Regulatory Guide 8.39
- NRC policy on extravasation
- ACMUI Bylaws



# Authorized User Training and Experience (T&E)

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- 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

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- “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

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- Root cause and corrective actions
- Pick lists vs narrative fields
- Timeliness of record completion and closure
  
- Subcommittee report will be discussed at September ACMUI meeting.

# NRC Extravasation Policy

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- Published on May 14, 1980
  - Rulemaking on misadministrations
- What else happened that week?
  - Sports
  - Entertainment
  - Nature

# NRC Extravasation Policy

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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

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- “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

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- 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

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- **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