ACMUI Update

Megan Shober
Agreement State Representative
Advisory Committee on the Medical Uses of Isotopes (ACMUI)

August 15, 2018
Outline

• Background
• Reports
• Upcoming 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

- Radiation Oncologists (2)
- Diagnostic Authorized Users (2)
- Nuclear Medicine Physician
- Radiopharmacist
- Medical Physicists (2)
- Health Care Administrator
- Patients' Rights Advocate
- FDA Representative
- Agreement State Representative
ACMUI Meetings

• ~5 meetings per year
  - In-person (spring and fall)
  - Teleconferences
• Open to the public
• Transcribed
ACMUI members are appointed to subcommittees for special topics.

- Rulemaking
- New technology
- Medical events
- Dosimetry
- Medical policy statement
- Patient intervention
- Electronic signatures

Subcommittee reports are discussed in public meetings.
Comments on draft training and experience SECY paper

Training and experience for all modalities

Physical presence requirements for the Leksell Gamma Knife Icon™

Nursing mother guidelines for the medical administration of radionuclides

https://www.nrc.gov/reading-rm/doc-collections/acmui/
2018 Subcommittee Reports

ACMUI

Authorized user training and experience

NRC

RCPD-18-003 (SECY paper)
2018 Subcommittee Reports

ACMUI

Gamma Knife physical presence

NRC

Revising 35.1000 guidance for Perfexion™ and Icon™
2018 Subcommittee Reports

ACMUI

Nursing mother guidelines

NRC

Revising Appendix U of Medical NUREG
When the Commission approved the latest 10 CFR 35 rule package, they directed NRC staff to re-examine T&E requirements for authorized users.
Limited scope authorized user?
Authorization by isotope?
Hours of experience?
How to approve for the whole category of 35.390?
Other concerns?
Questions?

megan.shober@wisconsin.gov
920-448-5346