

History, Authority and Current Issues of the ACMUI

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What is the ACMUI?

- Advisory Committee on Medical Use of Isotopes
- Advisory to the Medical Branch of the U.S. Nuclear Regulatory Commission
- <http://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html>

What is the ACMUI?

- Established in 1958
- Advises NRC on policy and technical issues that arise in the regulation of medical uses of radioactive material in diagnosis and therapy
 - emphasis on advisory
 - method for obtaining stakeholder input

Reporting Relationship



History

- Atomic Energy Act 1946
- Subcommittee on Human Applications 1948
- Atomic Energy Act Amended 1954
- Human Subcommittee
superseded by ACMUI 1958
- First civilian chair, Barry Seigel, M.D. 1994
- First RSO representative, R. J. Vetter 2000
appointed Vice-Chair 2006

Membership

[3-y terms]

Agreement State
Representative
FDA Representative
Health Care Administrator
Medical Physicist, Nuclear
Medicine
Medical Physicist,
Radiation Therapy

Nuclear Cardiologist
Nuclear Medicine Physician
Nuclear Pharmacist
Patients' Rights Advocate
Radiation Oncologist -
Brachytherapy
Radiation Oncologist -
Gamma Knife
Radiation Safety Officer
[Designated Federal Official]

Member Responsibility

- Membership is gained through a formal nomination and selection process.
- Members are appointed by the Director, Office of Federal and State Materials and Environmental Management Programs as Special Government Employees (SGEs)
- Terms are 3 years; usually reappointed for an additional term
- Expected to represent views of profession

Meetings

- Operational practices are governed by the provisions of the Federal Advisory Committee Act (FACA)
 - Open meetings; minutes published
 - Conflict of interest rules
- Committee meetings: public notice; open to the public; public may request an opportunity to comment during committee meeting

Meetings

- Five meetings per year, three of which are teleconferences (plus subcommittees).
- ACMUI may add items to agenda
- Members of public may request to present to ACMUI; NRC must approve.
- Members of public may comment during ACMUI meetings.
- ACMUI meets with Commission annually.

Regular Reports

- Medical events
- Status of active petitions for rulemaking
- Status of specialty board recognition
 - Medical boards
 - Pharmacist
 - Physicist boards
 - Radiation Safety Officer boards

Medical Events - 2007

■ 35.300 Unsealed Radiopharmaceuticals:

- I-131 NaI 5
- I-131 Bexxar 1 (I-131 monoclonal antibody)
- Y-90 Zevalin 1 (Y-90 labeled antibody)

■ Conclusions:

- I-131 error rate very small at 0.04%
- Human error is main contributing factor

Medical Events - 2007

■ 35.400 Manual Brachytherapy:

- I-125 5
- Pd-103 1
- Cs-137/Ir-192 1

■ Conclusions:

- Inadequate identification of prostate boundary
- Inadequate training on use of Mick applicator

Medical Events - 2007

- 35.600 Remote Afterloaders, Teletherapy
 - HDR 14 (2006: 17/160,000 treatments = 0.01% or 5.2 sigma; 6 sigma = 2.7 errors)
- Conclusions – human error
 - Wrong catheter
 - Wrong catheter length entered
 - Wrong dose, isodose or step size selected
 - Wrong treatment plan



Medical Events - 2007

- 35.600 Remote Afterloaders, Teletherapy
 - Gamma knife 2
- Conclusions
 - Wrong isodose selected
 - Image reversed



Petitions for Rulemaking

- Ritenour Petition to amend Part 35 to recognize:
 - Medical physicists certified by ABR or ABMP before Oct 24, 2005 as grandfathered
 - Diplomates certified by named boards in former Part 35, Subpart J, for RSO
 - Included ABHP, ABR, ABSNM

The Issue

- Boards not recognized prior to certain dates, e.g. ABHP made an exception to their admission criteria in 2004. Consequently, NRC won't recognize Board prior to that date.
- Thus, for CHPs certified prior to 2005 to qualify for RSO, they must complete alternate pathway including attestation from a preceptor RSO

Result

“NRC concluded that revisions made to the regulations in 2005 may have inadvertently affected a group of board certified professionals.”

Specialty Boards

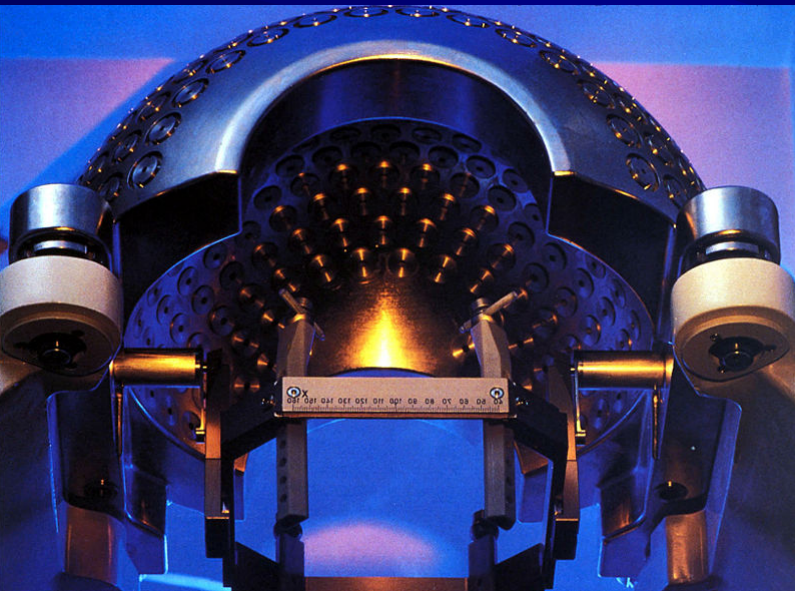
<u>Board</u>	<u>Recognition Date</u>
ABHP	Jan 05
ABMP	*
ABR – Physics	Jun 07
ABR – Rad Onc	Jun 07
ABR – Diag Radiol	Jun 06

*Awaiting input from ABMP

Recent Topics

■ Elekta Perfexion™

- 4th generation gamma knife with internally adjustable collimators



Security of $^{137}\text{CsCl}$ Irradiators

- Trustworthiness & Reliability
- Local criminal records check
- Fingerprinting
- FBI criminal records check
- Increased physical security



^{90}Y Microsphere Guidance

- Hepatocellular carcinoma
- Physician training
- Role of interventional radiologist

Meeting with Commission

- April 29, 2008
 - 10 CFR 35 T&E Implementation Issues
 - Fingerprinting Orders for Increased Controls

RSO Representative

- Vetter term expires 9/30/2009
- Federal Register: September 4, 2008
Volume 73, Number 172 Page 51649
- Submit electronic copy of resume or curriculum vitae to Ms. Ashley Tull,
ashley.tull@nrc.gov

THE END

