

COMMISSION BRIEFING SLIDES/EXHIBITS

**MEETING WITH ADVISORY COMMITTEE
ON THE MEDICAL USES OF ISOTOPES (ACMUI)**

MAY 28, 2003



ACMUI MEETING WITH THE U.S. NUCLEAR REGULATORY COMMISSION

May 28, 2003



OVERVIEW

Dr. Manuel D. Cerquiera, M.D.
ACMUI Chairman

Pending Vacancies

- Nuclear cardiologists
- Agreement state representative
- Patient advocate

Creation of ACMUI Vice-Chair

- Establish orderly transition
- Allows Chair to take more active role on issues dealing with own subspecialty
- Supported by Committee and staff

ACMUI/Staff Interactions

- Implementation of follow-up conference calls to review action items from prior meeting
- Discussion held with staff regarding better access to Commissioners when Committee recommendations were not being supported

Implementation of Revised Part 35

- Training and Experience (T&E) operating under both old and new requirements
- T & E Subcommittee recommendations submitted and under revision
- Important to keep in timely fashion to have new Rulemaking in place by October 24, 2005, when continuation of old rule expires

Agreement States Compliance

- 7 States have adopted requirements compatible with revised 10 CFR Part 35
- Majority of others expect to meet August 24, 2005, deadline
- Greatest anticipated problem relates to T&E



ACMUI FEEDBACK ON THE NATIONAL MATERIALS PROGRAM

Ralph P. Lieto
Medical Physicist, ACMUI

Background

- Origin from 1999 Commission directive
- Working Group Report submitted in mid-2001
- ACMUI review/comment Fall 2002
- Pilot projects underway

ACMUI Support

- Blending of the “current program” and “Alliance” options
- Single agency setting standards for all radioactive material consistent with industrialized nations

ACMUI Support

- 3 of 4 Components strongly supported:
 - Use centers of expertise
 - Maintain an information infrastructure
 - Create a standing compatibility committee
 - Proceed with Implementation Plan for these

Areas of Concern

- Costs
- Regulation of Naturally Occurring and Accelerator Produced Radioactive Material (NARM)

Costs

- Assume: States can provide for the program
- Program expansion = cost savings?
- Cannot be funded by non-Agreement States, and existing fee-based mechanism
- Change in regulatory authority by Congress must include change in funding mechanism

Regulation of NARM

- Authority to regulate NARM needed
- Increase NRC concern vs. adversely affecting position emission tomography (PET)
- Potential increase regulatory burden
- PET: great potential & growth in diagnostic nuclear medicine



ACMUI T & E Recommendations

**Richard J. Vetter, Ph.D.
Radiation Safety Officer
ACMUI**

ACMUI T&E Subcommittee

Charge:

Develop proposal to establish board certification as default pathway

Commission-approved

- (a) Certification by board recognized by NRC or Agreement States (AS):
 - meets special criteria;
 - preceptor attestation; or
- (b)(1) training requirements; and
- (b)(2) preceptor attestation

Impact of Decision

- Default pathway through professional boards
- Boards listed on NRC Website
- Preceptor attestation

Impact of Decision

- ACMUI stands ready to assist NRC staff in addressing:
 - Preceptor attestation
 - Other issues that may arise

BACKUP SLIDE

Board Certification

Example: Radiation Safety Officer (RSO)

- Assess mastery of a body of knowledge and its applications and adequacy of judgment to independently practice medical health physics

BACKUP SLIDE

10 CFR 35.900-Temporary

Example: RSO must be:

- (a) cert. by a board from list; or
- (b)(1) training requirements; and
- (c)(2) one year experience under supervision of RSO or
- (c) Be an authorized user

BACKUP SLIDE

Current 10 CFR 35.50

Example: RSO must be:

- Cert. by board that meets (b)(1) and (b)(2); recognized by NRC/AS or
- (b)(1) training requirements; and
- (b)(2) preceptor certification; or
- (c) be an authorized user

BACKUP SLIDE

Unintended Consequences

- Increased burden on NRC and AS staff
- Marginalize board certification
- Undermine effective industry standards

BACKUP SLIDE

ACMUI T&E Subcommittee

- Briefed Commission February 19, 2002
- Appointed ACMUI February 20, 2003
Subcommittee

(Develop proposal establishing board
certification as default pathway)

BACKUP SLIDE:

ACMUI T&E Subcommittee

- Public meeting June 21, 2002
- Public meeting July 8, 2002
- Recommend to NRC August 1, 2002
- NRC Options Paper Oct. 30, 2002
- Commission Decision Feb. 12, 2003



EMERGING TECHNOLOGIES AND ISSUES

**Ruth E. McBurney, CHP
TX Department of Health
ACMUI**

ACMUI Subcommittee on Emerging Technologies

- Ruth McBurney, CHP, Chair
- Douglas F. Eggli, M.D.
- Leon S. Malmud, M.D.
- Subir Nag, M.D.

ACMUI Subcommittee on Emerging Technologies

- Sally W. Schwarz
- Jeffrey F. Williamson, Ph.D.
- Richard Vetter, Ph.D.
- Nekita Hobson

CHARGE

Provide NRC staff with recommendations on licensing guidance for new modalities that do not fit into Subparts D through H of 10 CFR Part 35.

INITIAL TASK

Provide input on licensing guidance for:

- Intravascular Brachytherapy
- GliaSite (TM) System
- Yttrium-90 Microspheres

ISSUES

- T&E for authorized user
- Team approach needed?
- Presence of team members
- Written directive contents
- Unique radiation safety procedures

FOLLOW-UP

- Input from stakeholders by July 2001
 - Society of Nuclear Medicine
 - American Society for Therapeutic Radiology Oncology (ASTRO)
 - American College of Radiology
- Further discussions by Subcommittee on licensing guidance
- Continuing communication with NRC staff on emerging technologies