

**COMMISSION BRIEFING SLIDES/EXHIBITS**

**MEETING WITH ACMUI**

**FEBRUARY 19, 2002**

**Presentation of  
Manuel D. Cerqueira, MD  
Chairman, ACMUI  
on 10 CFR Part 35**

**NRC Revisions:  
Balanced and Fair**

# **NRC's Approach**

- **Risk-Informed, Performance-based**
- **Significant stakeholder Input**
- **ACMUI involvement**

# **An Open Process**

- **Seven Public Workshops**
- **20 Professional Society Meetings**
- **Six ACMUI Discussions: full panel (2), subcommittee (4)**
- **Two Agreement State Workshops**

# **State Role**

- **Organization of Agreement States (OAS)**
- **Radiation Officers**
- **Part 35 Working Group**

# **Public Input**

- **225 written comments**
- **All documents on NRC Web site**
- **Working group meetings open**

# **The Result**

- **Reduced regulatory burden**
- **Eliminated unnecessary rules**
- **Decreased prescriptiveness**

# **Implementation of 10 CFR Part 35 In Agreement States**

**Ruth E. McBurney  
Texas Department of Health  
on Behalf of  
ACMUI**



# **Rulemaking Process**

- **Involvement of Agreement State staff in Working Group and Steering Committee**
- **Fair process that allowed for input from all stakeholders**

# **Implementation Issues**

- **Three years to implement**
- **Some rules needed now**
  - **LDR, HDR**
  - **New technologies**
- **Scheduling of rule changes will vary**

# **T and E Requirements for MD Authorized Users**

- **Recommend NRC cooperation with states to get immediate uniformity in requirements**
- **Approve Boards to facilitate uniformity**

# **Workforce Issues**

- **Maturing workforce similar to NRC**
- **Lack of trained personnel for licensing and inspection**
- **Attraction of new staff is difficult**

# **Nuclear Pharmacy Issues**

**Sally Schwarz, R.Ph., M.S.  
Washington University St. Louis  
on Behalf of  
ACMUI**

# **Radiation Safety Issues**

- **Pharmacists handling reactor produced and PET radionuclides**
- **ALARA issues for handling reactor produced and PET radionuclides**
- **Pharmacist shortage**

# **Pharmacist Training/Shortage Issue**

- **Pharmacy program now requires 6 year (previously 5 years)**
- **Overall need for pharmacists has increased, one area is PET**
- **To maintain ALARA at a lower level will require more pharmacists**

# **Addressing the Shortage**

- **Pharmacy Profession Curriculum including sufficient elective courses during 6 year program**



# **Addressing the Shortage**

## **Certificate Programs (after 6 y)**

- Purdue**
- University of New Mexico**
- University of Arkansas**

# **Addressing the Shortage**

- **Technician Training-**
  - **Specialization needed for nuclear**

# **Board Certification and Training & Experience Requirements**

**Jeffrey F. Williamson, Ph.D.**

**Washington University**

**on behalf of**

**ACMUI**

# **Major Concern**

- **Definition Conflict between**
  - **10 CFR 35.51 Authorized Medical Physicist (AMP)**
  - **Community's definition (ABR/ABMP certification in Radiation Oncology Physics)**

# **Board Certification**

- **Board certification: requires training and experience as specified in 10 CFR 35.51 (b)**
- **ABR/ABMP: Do not require experience with specific byproduct technologies HDR, teletherapy, stereotactic**

# **Unintended Consequences**

- **Marginalize board certification**
  - **Regulatory significance undermined**

# **Unintended Consequences**

## **Public health undermined**

- Formal training programs rare**
- Few opportunities for Co-60 device training**
- Exacerbate AMP shortages**

# Remedies

- **Short-term: unconditional grandfathering of current teletherapy physicists and acceptance of certification**
- **Long-term: rule-making initiative to replace “and” with “or”**



# **Backup slide: New 10 CFR 35: Physicist's view**

- **AMP definition recognizes role of physicist in assuring treatment quality/safety**
- **“wrong site” criterion repaired by “medical event” concept**

# **Backup slide: New 10 CFR 35: Physicist's view**

- **QA rules closer to practice standards**
- **Easier to add new uses & modalities**

# **Backup slide**

## **Qualified Medical Physicist**

- **Consensus definition: QMP = board certification + continuing education**

# **Backup slide**

## **Qualified Medical Physicist**

- M.S./Ph.D. + 2-6 years T&E  
under certified mentors +  
letters of reference**
- AAPM, ACR and ACMP view**

# **Backup: 35.51 AMP definition**

**a) Certified by recognized Board  
whose certification includes b)**

# **Backup: 35.51 AMP definition**

- a) OR has MS degree + 1 yr Rad  
Onc training + 1 yr experience  
under AMP including**
- HDR, teletherapy +  
Stereotactic duties**
  - Preceptor's statement**

# **Backup Slide**

## **Short-Term Remedies**

- **Supplementary training example**
  - **Undergo vendor training for Gamma Knife**
  - **Observe Gamma Knife cases at institution with functioning program**

# **Backup slide:**

## **35.600 AU T&E criteria**

- **certified by recognized Board which includes**
- **“...500 h practical experience..”**
  - **Reviewing calibrations, plans, specific to devices**



# **Backup slide: 35.600 AU T&E criteria**

- **Preceptor's statement for each modality**
- **Appears to conflict with ABR eligibility requirements**

# **Board Certification for Radiation Safety Officers**

**Richard J. Vetter, Ph.D.**

**Mayo Clinic**

**on behalf of**

**ACMUI**

# **Current 10 CFR 35.900**

**RSO must be:**

**(a) certified by a board from list**

**OR**

**(b) training requirements**

**AND**

**one year experience under  
supervision of RSO**

# **New 10 CFR 35.50**

**RSO must be**

**(a) certified by a specialty board  
that includes (b) & (c)**

**OR**

**(B) training requirements**

**AND**

**(C) preceptorship**

# **Unintended Consequences**

- **Increased burden on NRC staff**
- **Marginalize board certification**
- **Undermine effective industry standard**

# **Remedies**

- **Short term: Accept health physics certification by ABHP, ABMP, ABR, and ABSNM**
- **Long term: Rulemaking to remove 35.50(b) as a board requirement**

# **BACKUP SLIDE:**

## **The Problem (Examples)**

- **ABHP: doesn't focus exclusively on medical, thus no medical preceptorship required**

# **BACKUP SLIDE:**

## **The Problem (Examples)**

- **ABMP requires graduate degree without hours enumerated or written certification by preceptor RSO**



# **BACKUP SLIDE:**

## **Unintended Consequences**

- **Reduced pool of qualified RSOs?**
- **Reduce quality of practice?**
- **Undermine public health?**

# **BACKUP SLIDE:**

## **Board Certification**

- **Qualifications (examples):**
  - **ABHP: B.S. & 5 yrs experience similar to 35.50(b) + references**
  - **ABMP: M.S. & 6 yrs experience similar to 35.50(b) + references**

# **BACKUP SLIDE: Board Certification**

- **Assess adequacy of judgment and knowledge to independently practice medical health physics**