ACMUI Discussion of Part 35 Training and Experience Requirements

Douglas F. Eggli, M.D.
Nuclear Medicine Physician

Background

- ACMUI reviewed the training and experience requirements for Authorized Users (AUs), Authorized Nuclear Pharmacists (ANPs), Radiation Safety Officers (RSOs), and Authorized Medical Physicists (AMPs)

Goals

- Make the requirement commensurate with the risk
- Risk-informed/performance based vs. prescriptive

Initial Evaluation

- ACMUI: T & E subcommittee formed
- Initial discussions:
  - describe elements of training
  - Training provider
  - Attest to training adequacy

Initial Recommendations

- ACMUI: certifying boards should remain actively involved
- An alternate pathway developed

Training Programs

- ACMUI recommended that training programs would be responsible for developing a curriculum that would satisfy the broad educational and experience objectives required by the regulation

Training Programs

- ACMUI did not recommend a specific time allocation for individual curriculum components, rather specified the content to be mastered (performance based regulation)

Attestations

- Certifying boards: attest, not certify
- Certification of competence: legal ramifications

Attestation Recommendation

- Attestation be performed by the training director, who is responsible for similar attestations of training experience to the certifying boards

Attestation

- The NRC subsequently determined that the public interest would be best served by requiring an Authorized Individual to supply the attestation of training and experience.

Part 35 Rule Making

- Recommendations were offered for training requirements for all categories of Authorized Individuals
- The ACMUI recommendations were largely adopted by the Commission
- Proposed rule based on ACMUI recommendations

OAS Concerns

- Organization of Agreement States: concern over AU training and experience
- Concern hinged on specificity of didactic education requirements, not on 700 hrs

ACMUI Discussion

- Total hours reduced from 1000 to 700 is appropriate
- Distribution of training hours represented an area of concern for ACMUI

Reasons for ACMUI Concern

- Most clinical Nuclear Medicine in the US (subpart 200 and 300 uses) is performed by physicians trained and certified by the American Board of Radiology (approximately 70% of clinical volume)

Reasons for ACMUI Concern

- Because of competing demands for training time from new modalities, Diagnostic Radiology training programs will tailor training time in Nuclear Medicine to NRC requirements (700 hours)

Reasons for ACMUI Concern

- American Board of Radiology has indicated that it intends to require all Diagnostic Radiology residents be trained in subpart 300 uses
  - This means that subpart 390 T&E requirements have to be the basis for Radiology training

Reasons for ACMUI Concern

- ACMUI: 200 hours of didactic training was excessive
- Recommended 80 hours for subpart 300 uses.
- Recommendation was based on ACMUI members' experience

Reasons for ACMUI Concern

- Since total experience will likely be limited to 700 hours, practical and clinical experience time would be disproportionately reduced to accommodate a 200 hour didactic training requirement

Didactic Training

- Components of didactic (classroom and laboratory) training are not well defined
- Large didactic requirement leads to uncertainty (i.e., what qualifies as didactic training?)

Definition of Didactic

- Dorland's Medical Dictionary definition of didactic: "conveying instruction by lectures and books rather than by practice"
- Training directors need to be certain that the programs they design meet the intent of the regulation

Further Discussion with NRC Staff

- Because the T&E requirement for subpart 200 and 300 uses are to be prescriptive (quantitative), provide enough detail so that training directors can be certain of compliance

Summary: Medical Event Reporting Issues

Jeffrey F. Williamson, Ph.D.
Chair, ACMUI Medical Event Subcommittee

Subcommittee Charge

- Evaluate 20% Threshold in ME rule
- How best to communicate risk
- Permanent interstitial brachytherapy

Medical Event Subcommittee (MESC) activities

- Membership
- Two closed conference calls; two noticed public calls
  Consultant: Louis Potters, MD
- Recommendations: April 2005

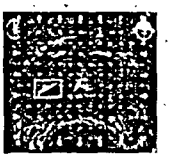
Outline

- Review ME issues in prostate permanent seed brachytherapy
- Review MESC consensus achieved to date
- Review issues still under discussion

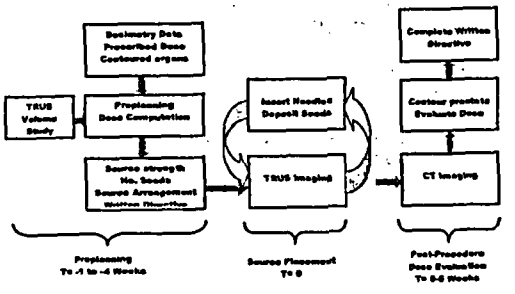
Image-Guided Source Insertion Procedure

- 18 gauge (1.3 mm diameter) needle for seed placement
- Ultrasound probe in rectum for needle guidance
- TRUS = Trans-rectal ultrasound imaging

TRUS Image Guidance

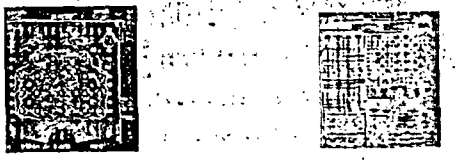


Prostate Brachytherapy Procedure Flow



Preplanning

- TRUS imaging 2 wks before implant
- Dose calculations to find needle loadings & seed strengths that deliver desired dose to clinical target volume (CTV)



Seed Insertion Procedure

- Patient anatomy may differ from preplan
- AU must be free to adapt preplan to anatomy imaged during procedure

Post-Procedure Dose Evaluation

- CT imaging: 0-30 days later
- Contour CTV and organs at risk & calculate doses
- Post-implant doses, e.g., D_{90}, most definitive estimate of delivered dose

Current ME Definition

10 CFR 35.3045

- ME = byproduct material administration, in which
  - |Delivered - Prescribed|> 50 Rem AND > 20% OR
  - Dose to extra-target site > expected (planned) dose by 50 Rem AND 50%

Is 20% Level Justifiable?

MESC consensus

- For temporary implants, 20% is a reasonable regulatory action level
- Permanent Implants: No

Rationale: Prostate

- Variability in Post-Implant CT vs. written directive dose comparisons
  - CT vs. US CTV: 50% differences
  - Large CT contouring variations
  - Long/variable interval from Implant to dose calculation
  - legitimate preplan modifications

Other Permanent Implant Issues

- WD: 35.40(b)(6)(ii) allows AU to specify No. sources and dose at any time post-Implant
- Wrong site ME: unenforceable

MESC Proposal

- Define ME in terms of where sources are implanted rather than dose delivered
- Recommendation 1

MESC Proposal

- Recommendation 2: Replace wrong site and target volume ME definitions

MESC Proposal

- Recommendation 3: For permanent implants amend 35.40(c) and (b)(6)(iii) to require completion and any revision of WD within 1 working day of source insertion

Rationale: Recommendations 1-3

- Determining fraction of seeds
- Determine seed fraction intraoperatively
- Limiting WD revisions

Risk Communication

MESC proposals under discussion

- Recommendation 4: Treat ME strictly as QA performance surrogate divorced from patient harm

Rationale Rec 4:

- ME reporting perception
- AU reporting dilemma

Rationale Rec 4:

- Industry practice
  - Errors alone not grounds for punishment
  - Error reports used to improve overall process
  - QA deliberations not discoverable

Unresolved Issues

- Dose calculation errors
- Williamson: Add dose-calculation error ME pathway limited to preplanning
  - ME = any calculation ⇒ error in source strength WD > 20%

Other ME issues

- Is current wrong-site ME criterion workable and justifiable for other types of brachytherapy and external beam treatments?

ACMUI Review of ICRP 2005 Recommendations

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

Extent of Comments

- Comments limited to items of greatest interest to ACMUI
- No comments on environmental recommendations

Justification

ICRP 2005 on justification of medical exposure:

- Justification of practice
- Justification of procedures
- ACMUI agrees

ICRP Constraints

- Restrictions on dose: constraints
- Achieving constraints: obligatory
- Exceeding constraints: failure
- ACMUI position

Example of Constraint

ICRP recommended declared pregnant worker constraint: 1mSv

ACMUI view:

- Current limit of 5 mSv is safe
- 1 mSv may be appropriate ALARA goal for some; not constraint

Typical Doses to Medical Personnel

- Cardiac Lab
- PET
- Nuclear Medicine

Public Dose Constraint

- ICRP: a few mSv reasonable but don't be rigid
- NRC: limit of 5 mSv to member of public from radioactive patient.
- NCRP recommends 5 mSv; 50 mSv if instructed & monitored.

Public Dose Constraints

- ICRP: 0.3 mSv constraint problematic; exorbitant cost
- NCRP: 0.25 in general; 1.0 for medical facilities shielded per NCRP recommendations
- ALARA still works

Public Dose Limits

- NCRP Statement 10 (2004):
  - 1 mSv limit to members of public
  - 5 mSv recommended for caregivers of radiation therapy patients
  - 50 mSv limit; trained & monitored

Worker Dose Limits

- Pregnant worker: 1 mSv per term problematic, risk very low
- Workers: 20 mSv problematic for some
- ACMUI supports NCRP recommendation & current NRC annual limit of 50 mSv

Conclusions

- ICRP proposed constraints confusing and problematic
- ICRP proposed occupational limits problematic for some modalities

ACMUI Report on Dose Reconstruction

Jeffrey F. Williamson, Ph.D.
Chair, DRS Subcommittee

Subcommittee Charge

- Independently review Region 3's dose evaluation
- Review the alternate dose reconstruction methodology
- Make recommendations regarding dose reconstruction

DRS SUBCOMMITTEE

J. Williamson, PhD Chair
D. Eggli, MD
N. Hobson
L. Malmud, MD
O. Suleiman, PhD
S. Schwarz, RPh

St. Joseph's Hospital Incident

- 285 mCi I-131 orally administered
- Daughter's exposure
- Reg III: Daughter's exposure = 15 rem
- SNM: too conservative

ACMUI DRS SC Investigations

- Review Reg III calculations,
- Review/critique Marcus/Siegel article
- Interview relevant parties and review documents

Findings

- 15 rem: most conservative estimate possible that is not totally implausible
- Distance reconstruction
- DRS estimate: 9 rem for Reg III's dwell-time scenario

Findings: continued

- SJH disputes Reg III dwell-time scenario
- DRS: reduces DDE to 4-6 rem
- Inspection report improvement

Siegel/Marcus Critique

- Use more sophisticated DR tools, e.g., distance reconstruction
- Use EDE, not DDE, as regulatory endpoint
- DRS: overly simplistic approximations used

SNM vs. ACMUI DR

- Distance Reconstruction factor
- EDE vs. DDE factor
- Continuous decay factor
- Various other factors

ACMUI Recommendations to NRC Staff

- Doses near regulatory limit
- Licensee disputes NRC DR
- Plausibility of findings is suspect
- Usual approximations suspect

ACMUI Recommendations to NRC Staff

- Use EDE as DR regulatory endpoint for CFR 20 compliance
- Use EDE/DDE ranges and/or justify rejection of Licensee scenario
- Exempt caregivers

ACRONYMS

ACMUI - Advisory Committee on the Medical Uses of Isotopes

ALARA - As Low As Reasonable Achievable

AMP - Authorized Medical Physicist

ANP - Authorized Nuclear Pharmacist

AU - Authorized User

CFR - Code of Federal Regulations

CT - Computed Tomography

CTV - Clinical Target Volume

DDE - Deep-dose Equivalent

DR - Dose Reconstruction

DRS - Dose Reconstruction Subcommittee

EDE - Effective Dose Equivalent

ICRP - International Commission on Radiological Protection

ME - Medical Event

MESC - Medical Event Subcommittee

NCRP - National Council on Radiation Protection and Measurements

OAS - Organization of Agreement States

PET - Positron Emission Tomography

QA - Quality Assurance

Rec - Recommendation

RSO - Radiation Safety Officer

SC - Subcommittee

SJH - St. Joseph's Hospital

SNM - Society of Nuclear Medicine

T & E - Training and Experience

TRUS - Trans-Rectal Ultrasound Imaging

WD - Written Directive