NRC Update: Part 35 Training and Experience and Who's the ACMUI and Why Should a Medical Physicist Care?

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CAVEAT!

- Beware
- Warning
- Notice
- Qualification

History

- Over seven years were spent in developing the regulations – almost 10 years on training and experience (T&E) requirements.

- Agreement states and stakeholders and ACMUI participated in the rule development process.

Current Part 35 Status

- Revised Part 35 (published Fed Register on April 24, 2002) was effective October 24, 2002, for Non-agreement States except for T&E Provisions

- Revised T&E provisions effective April 29, 2005, for Non-agreement States

- Subpart J (old Part 35 T&E with listed Boards) extended until October 24, 2005
Current Part 35 Status


Agreement State Implementation Schedule:
- Agreement States must implement revise Part 35 (pub. 4/24/02) by 10/24/05.
- Agreement States will have 3 years to implement the final T&E provisions, i.e., by 4/29/08

General T&E Requirements

- Compatibility B for Agreement States
  - requires adoption by the State

- Provides two pathways to become authorized:
  1) Board certification
     - Procedures on NRC website for certifying boards [ABR, ABMP, AB(S)NM, ABHP] to submit for recognition
     - Recognized Boards will be listed on NRC website, not in regulation
  2) Alternate Pathway

- Preceptor Statement required for board certification and alternate pathways
  - Signed attestation of training, level of knowledge to function independently by individual with same authorization
- Grandfathering provided
Part 35 Sections Changed

- Subpart A—General Information
  - § 35.2 Definitions

- Subpart B—General Administrative Requirements
  - § 35.50 Training for Radiation Safety Officer
  - § 35.51 Training for Authorized Medical Physicist
  - § 35.57 Grandfather Provision
  - § 35.59 Recentness of Training

Preceptor Definition, § 35.2

- Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, medical physicist, nuclear pharmacist, or a Radiation Safety Officer.

Radiation Safety Officer (RSO)

Definition:
1) Meets the T&E requirements in Part §35.50;
   or
2) Is identified as an RSO on existing NRC or Agreement State license.

Radiation Safety Officer (RSO) T&E – Board Recognition

1) Is certified by a recognized specialty board;
   and
2) Preceptor Statement requirement;
   and
3) Types of Use training requirement of this section §35.50 (a), (d), (e)
RSO – Board Recognition

For certification process recognition, a specialty board shall require all RSO candidates:

1) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science; and

2) Have 5 or more years of professional experience in health physics with at least 3 years in applied health physics; and

3) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry;

OR

For certification process recognition, a specialty board shall require all RSO candidates:

1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and

2) 2 years of full-time practical training and/or supervised experience in medical physics
   - Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or
   - In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of Authorized User physicians; and

RSO – Board Recognition (cont’d)
3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety;

RSO T&E– The Alternate Pathway

- Completed a structured educational program consisting of both:
  1) 200 hours of classroom and laboratory training in the following areas:
     - Radiation physics and instrumentation;
     - Radiation protection;
     - Mathematics pertaining to the use and measurement of radioactivity;
     - Radiation biology;
     - Radiation dosimetry;

- One year of full-time radiation safety experience under the supervision of the Radiation Safety Officer on a license that authorizes similar type(s) of use(s) of byproduct material including:
  - Shipping, receiving, and performing related radiation surveys;
  - Using and performing checks for proper operation of instruments;
  - Securing and controlling byproduct material;
  - Disposing of byproduct material

RSO T&E– The Alternate Pathway

- If a medical physicist (not AMP) certified by a recognized board under §35.50(a); and
- Has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer; and
- Preceptor Requirement; and
- Types of Use training requirement of this section;

§35.50(c)(1)
RSO T&E – The Alternate Pathway
For AMP, ANP, or AU

- an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license; and
- has experience with the radiation safety aspects for similar types of use for which the individual has Radiation Safety Officer responsibilities; and
- Preceptor Requirement; and
- Types of Use training requirement.

§35.50(c)(2)

RSO T&E – The Preceptor Statement

- Written attestation that the individual has:
  - satisfactorily completed the T&E requirements in § 35.50; and
  - has achieved a level of radiation safety knowledge sufficient to function independently as a RSO for a medical use licensee
- Signed by preceptor RSO

§35.50(d)

RSO T&E – Types of Use Training Requirement

- Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval.

§ 35.50 (e)

RSO T&E – Types of Use Requirement

- This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

§ 35.50 (e)
Authorized Medical Physicist (AMP) Definition, § 35.2

- Authorised medical physicist (AMP) is a new designation
  1) Meets the T&E requirements in Part 35.51;

- OR
  2) Is identified as an AMP or teletherapy physicist on existing NRC or Agreement State license

AMP T&E–Board Pathway, §35.51

- (a) Is certified by a recognized specialty board . . . and
- (b)(2) Preceptor statement requirement and
- (c) Modality specific training for which authorization is sought—new requirement

AMP – Board Recognition

- For certification process recognition, a specialty board shall require all AMP candidates:
  1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

AMP – Board Recognition (cont’d)

- 2) Have 2 years of full-time practical training and/or supervised experience in medical physics:
  - (i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or
  - (ii) In clinical radiation facilities providing high-energy, external beam therapy and brachytherapy under the direction of Authorized User physicians;
AMP – Board Recognition (cont’d)

3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery;

OR

§35.51(a)

AMP T&E–Alternate Pathway

- Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and
- completed 1 yr of full-time training in medical physics; and
- an additional year of full-time work experience under the supervision of an AMP for the type(s) of use for which the individual is seeking authorization.

§35.51(b)(1)

AMP T&E–Alternate Pathway

- This training and work experience must be done in clinical radiation facilities that provide high-energy, external beam therapy and brachytherapy services and must include:
  - Performing sealed source leak tests and inventories;
  - Performing decay corrections;
  - Performing full calibration, periodic spot checks, and radiation surveys of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units, as applicable

AMP T&E– the Preceptor Statement

- Written attestation that person has:
  - satisfactorily completed the T&E requirements, and
  - has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

§ 35.51(b)(2)
AMP T&E– the Preceptor Statement

- The written attestation must be signed by a preceptor AMP who meets the requirements for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

AMP T&E– Training for Types of Use

- Training for the type(s) of use being sought includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

- Training requirement may be met by satisfactorily completing:
  - a training program provided by vendor, or
  - by training supervised by an AMP authorized for the type(s) of use for which authorization is sought.

§35.51(c)

The Grandfather Provision, §35.57

- If identified on NRC or Agreement State license as RSO, a teletherapy or medical physicist (before 10/24/02), or an authorized medical physicist (10/24/02-4/29/05), or a nuclear pharmacist need not comply with the new T&E requirements. (i.e., §§35.50, 35.51, or 35.55)

Grandfather Provision - Problem

- Most medical physicists are not listed on an NRC or Agreement State licenses whether specific or broad scope

- Conference of Radiation Control Program Directors (CRCPD) developed a suggested license amendment for adding medical physicists to state licenses. (7/15/05)

http://www.crcpd.org/free_docs.asp
Recentness of Training

- §35.59 - The training and experience specified in Part 35 must have been obtained:
  - within the 7 years preceding the application date, or
  - must have had related continuing education and experience since the required training and experience was completed.

Next Steps

- Professional societies (AAPM, SNM, ASTRO, HPS, etc.)
- Need to work with certifying boards to ensure NRC grants board recognition status for all certificates issued (current and historical) for both AMP and RSO.

ACMUI

- Advisory Committee on Medical Use of Isotopes
- Est. 1958
- Purposes:
  - "provide advice on policy & technical issues in regulating the medical use of byproduct material"
  - Consulting services
  - Bring issues to NRC staff attention
- Bylaws

ACMUI - Membership

1. Healthcare Administrator
2. Radiation Oncologist
3. Radiation Oncologist - brachytx
4. Nuclear Medicine Physician
5. Radiopharmacist
6. Nuclear Cardiologist
7. FDA Representative
8. Radiation Safety Officer
9. Radiation Therapy Physicist
10. Nuclear Medicine Physicist
11. Agreement State Gov’t
12. Patient Advocate
13. Interventional Cardiologist
ACMUI

- Meetings
  - 2 NRC HQ, Rockville, MD
  - 2-3 Teleconference
  - Annual briefing of Commissioners
- Reports to the Director, Div. of Industrial & Medical Nuclear Safety, Office of NMSS
- Biennial self-evaluations

ACMUI – Recent Activities

- Part 35 Training & Experience Revision
- Dose estimate reconstruction to member of general public
- Amending the Abnormal Occurrence (AO) Criteria for Medical Events
- I-131 Therapy Incidents review
- Medical Event (ME) definition revision
- Consult on T&E of individuals
  ♦ subcommittee

Dose Reconstruction

- History
  - Patient’s daughter spent several hr/day in close proximity to dying patient
  - NRC RIII: Daughter’s dose = 15 rem
  - Critical SNM report: too conservative by factors of 1.6, 7.1 or 17

Subcommittee Charge

- Independently review NRC Region III dose evaluation
- Interview RSO and inspectors; review licensee documents
- Review NRC RIII calculations
  - independent, limited Monte Carlo simulations
- Review the alternate SNM dose reconstruction (DR) methodology
- Make recommendations regarding DR process
**Recommendations to NRC Staff**

- Estimated dose 4-9 rem
- More sophisticated DR tools indicated when
  - Doses near regulatory limit
  - Licensee disputes NRC DR
  - Plausibility of DR assumptions suspect and data not available
  - Usual approximations suspect

**Recommendations to NRC Staff**

- Use EDE as DR regulatory endpoint for CFR 20 compliance (RIS 03-04)
- For disputed DRs, use EDE/DDE ranges and/or justify rejection of licensee scenario
- NRC should exempt caregivers from 500 mrem limit when warranted by humanistic/medical considerations

**I-131 Therapy Incidents Review**

- Subcommittee Charge
  - Review I-131 therapy incidents in NRC NMED for common themes or systematic problems
  - Recommend measures which might further reduce I-131 administration incidents

**Observations**

- The number of incidents is small compared to the total number of annual therapeutic administrations in the US
  - Fewer than 10 per year
  - No institution has more than one error
- Errors reported were human errors
  - Failure to pay attention to detail
  - Failure to follow established policies and procedures
  - Miscommunications
Recommendations

Reflect an effort to further reduce human error
- Patient verification procedures similar to blood administration
- Verbal orders should not be permitted in any step of the therapeutic dosage administration process
- The dosage to be administered must be verified against the written directive prior to administration

Recommendations (cont’d)

- Re-verify the dosage in a dose calibrator on site prior to administration
- Communication should be strengthened between the Authorized User and the individual administering the dosage
- The administering technologist should review the treatment plan with the AU prior to dosage administration

Recommendations (cont’d)

- Documentation in NMED needs to be improved
  - Need to know causes/contributing factors:
    - Was AU present?
    - Were multiple dosages on site?
    - Was the dosage assayed on site?
    - Verbal orders?

Medical Event (ME) Revision

CURRENT SITUATION
- “completion of procedure” (Written Directive) for permanent implants inconsistent
- Recognize NRC OGC interprets “dose” = total dose = total source strength (activity)
- Dose based, “wrong site” ME criterion impractical to apply for permanent implants
- Is ±20% appropriate risk based reporting threshold for medical events?
Medical Event Recommendations

- ACMUI position that ±20% reasonable for all modalities except absorbed dose written directive of permanent implants
- Define ME reporting for permanent implants in terms of “total source strength”
  - Written Directive will need to specify activity

- Revise the “wrong site” ME criterion to ±20% of total source strength > 3 cm from treatment site boundary
- Using source-strength-based criterion, reasonable “completion of procedure” = patient released from licensee control
- Add limited dose-based ME criterion: dose calculations to determine the total source strength in error > ±20%

Medical Event Recommendations

- Remove stigmatizing, negative response of ME reporting
  - Replace 24 hr reporting to Op Ctr with written 7 day notice to Regional Office unless patient harmed
- ±20% threshold is a reasonable quality performance indicator, NOT an indicator of patient harm

- Amend §35.3045(e) re: patient notification unless harmed or future medical treatment affected
- Make ME reporting & enforcement process analogous to medical QA practice of follow-up and review.
ACMUI – Future Issues

- NRC assumption of regulatory authority for ALL radioactive materials
- Agreement States
- Medical technology developing faster than regulations can address
  - Ex/ Tx microspheres, IVBT
  - NRC wants to avoid major rulemaking
  - Requires scientific fundamentals, performance-based problem solving, and a “team approach”

Web Addresses

- NRC Medical Uses Toolkit:  
- NRC Part 35 Regulation:  
- NUREG 1556, Volume 9:
- Suggested State amendment for medical physicist
  - http://www.crcpd.org/free_docs.asp

References