

**Steering Group (SG) Directions to the Working Group  
Rulemaking on Revisions to 10 CFR Part 35 (T&E)  
June 23, 2004, 1:00 P.M. – 2:30 P.M.**

The SG discussed possible resolutions to the following issue:

The NRC published for public comment proposed amendments to 10 CFR Part 35, “Medical Use of Byproduct Material,” to revise requirements for training and experience (T&E) (December 9, 2003, 68 FR 68549). Some commenters on the proposed rule advocated a change to the requirements in §§ 35.190, 35.290, and 35.390 specify the number of hours of T&E devoted to didactic (classroom and laboratory) training for individuals to qualify as Authorized Users. One commenter made a similar recommendation for individuals to qualify as Authorized Nuclear Pharmacists under § 35.55.

The SG provided the following guidance to the working group (WG) to resolve the issue:

1. Provide to the steering group, in four weeks, recommendations for revising the draft-final rule on T&E. Use the following as guidance in considering alternative approaches:
2. Focus on radiation safety in re-examining methods by which the adequacy of T&E is ensured.
3. Consider the following approaches to evaluating the adequacy of T&E:
  - a. Pro and cons of requirements for a minimum number of hours of didactic training in §§ 35.55, 35.190, 35.290, and 35.390.
  - b. Consider the pros and cons of an examination as another option to ensure radiation safety.
  - c. Review the specification and interpretation for T&E in basic radionuclide handling technique, e.g., 700 hours in § 35.390, as it relates to training in clinical / medical vs. radiation safety skills.
4. Review the pros and cons of communicating revised recommendations / requirements in guidance (SOCs) or in regulations.
5. When reviewing pros and cons of various approaches, consider the question, “Does risk justify the regulatory burden that is imposed?”
6. Involve the Subcommittee on T&E of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), followed by the full ACMUI in resolving the issues, with particular attention to radiation safety as it relates to specifications for number of hours of didactic training.