Recommendations of Working Group (WG)
Rulemaking on Revisions to 10 CFR Part 35 (T&E)
August 23, 2004

The WG reconsidered options previously presented to the SG on July 27, 2004 (Attachment 1), for resolving concerns from Agreement States relating to specifying a minimal number of hours of didactic T&E in §§ 35.55, 35.190, 35.290, and 35.390. Five WG members support the recommended option, two of which qualify their recommendation. Two members dissented from recommending addition of a specification for hours of didactic T&E; dissents appear in the attachments.

Recommended Option (with dissenting opinions): Option 5

Option 5: Provide Specifications for Minimal Hours of Didactic T&E in Revised Regulations – Alternate Pathway Only

Under this option, the addition of a specification of didactic hours to the regulations would only apply to the alternate pathway and would NOT be part of the criteria for recognition of board certifications. The specification for number of hours recommended by the Agreement States, ACMUI Subcommittee, and proposed by the WG appears in the table below.

Recommendations for Minimum Number of Hours of Didactic Training				
Section	Didactic and Experience (hr)	Recommended Minimal Didactic Training (hr)		
		Agreement States	ACMUI Subcommittee	Working Group *Alternate Pathway Only*
35.55	700	200	zero; 25-33 %	200
35.190	60	8	zero; 25-33 %	8
35.290	700	80-100	zero; 25-33 %	80
35.390	700	200	zero; 25-33 %	200

Discussion

Seven WG members voted for an option. Five of the seven members of the WG agree that the Option 5 approach is an acceptable compromise, but have different opinions about the 80 and 200 hours didactic training for §35.290 and §35.390, respectively. The recommended option was chosen because it was believed to be most acceptable considering the diverse points of view among stakeholders, such as ACMUI and Agreement States. Dissents of two WG members appear in Attachments 6 and 7.

Three WG members (representing ADM, OCIO, and OE) did not vote for a recommended option because they believe that their main focus of attention should be the appropriateness of the Federal Register notice, information collection requirements, and enforcement issues, respectively.

Preferences of Two WG Members Who Joined in the Consensus for Option 5

One voting member, although agreeing to go along with Option 5, prefers a "no change" option (i.e., do not specify didactic hours, which is not among the options previously presented to SG). Of the six options presented to the SG on July 27, 2004, this member would also prefer Option 6 over Option 5 because of a belief that Option 6 is more defensible, i.e., more easily justifiable, as there is greater potential safety benefit of adding prescriptiveness to the requirements for §35.300 use (primarily therapeutic) than there is for §35.100 and §35.200 use (diagnostic).

Another member prefers 80-100 hours for §35.390.

The member representing OGC agrees with the Option 5 approach but did not express any opinion on the number of didactic hours, as this member believes that this is a technical matter that must be decided by the staff.

Issue on Whether to Re-publish for Comment

The WG discussed the rule should be republished in the Federal Register for public comment if the NRC adopts Option 5. WG members have different opinions. The WG requested that the OGC representative obtain OGC's view on this issue.

The OGC representative subsequently advised that this rule is not required to be republished for comment because the change does not bring up something totally new that was not encompassed by the proposed rule, and the commenters had been afforded an opportunity to provide comments.

However, some members of the WG still believe that there are critical policy considerations necessitating republication of the rule.

Suggested Rule Text and Changes to Guidance and Implementing Procedures

The WG also developed suggested rule text for Option 5, statements to be included in the Supplementary Information, and changes to the procedures for implementing Part 35 Training and Experience Requirements, as described below:

1. Suggested rule text for § 35.190 is presented in Attachment 2. Similar rule text would be used for other sections.

2. To address concerns of Agreement States relating to adequacy of certification examinations for evaluation of radiation safety competency:
   a. The Supplementary Information would include additional guidance about the expectations of the NRC regarding the content of examinations and the

structure/content of training programs. (See Attachment 3 for suggested language for Supplementary Information.)

b. Implementation procedures would be revised to add instructions to boards to submit information during their applications to ensure that their examinations address radiation safety. (See Attachment 4 for suggested language for implementation procedures.)

4. Relative merits (Pros & Cons) of specifying minimal hours for alternative pathway only are presented in Attachment 5.

Information from Mr. Frazee's Poll of Agreement States

Agreement State representatives on the WG will present information at the SG meeting on 8/23/04.

A member of the WG conveyed partial results of the poll of Agreement States relating to concerns about the adequacy of examinations and this issue was addressed as identified above in items 2.a. and 2.b.

Attachment 1
Summary of Options Presented to SG on July 27, 2004

Option 1. Provide the NRC's Expectation for Minimal Hours of Didactic T&E in Guidance

Option 2. Clarify Requirements for Didactic Training Through Revision of the Preceptor Statement (Revise in Regulations)

Option 3. Assessing Adequacy of T&E by Conducting Examinations – Require Only for Alternate Pathway

Option 4. Provide Specifications for Minimum Number of Hours of Didactic T&E in Revised Regulations (Apply to Both Pathways)

Option 5. Provide Specifications for Minimal Hours of Didactic T&E in Revised Regulations – Alternate Pathway Only

Option 6. "Blend:" Provide Specifications for Minimal Hours of Didactic T&E in Revised Regulations – Alternate Pathway and § 35.390 ONLY, PLUS Update Guidance in SOCs on NRC's Intent

Attachment 2
Suggested Rule Text for 35.190

§ 35.190 Training for uptake, dilution, and excretion studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who–

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and meets the requirements in paragraph (c)(2) of this section. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) **Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section**;

(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety .....

(b) Is an authorized user under §§ 35.290, 35.390, or, before October 24, 200~~4~~ **5**, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements; or

(c)(1) Has completed 60 hours of training and experience to include **a minimum of 8 hours of classroom and laboratory training** in basic radionuclide handling techniques **and radiation safety** applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include–

(i) Classroom and laboratory training in the following areas–

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, ...

Attachment 3
Suggested Language for Supplementary Information

The Supplementary Information would include the following guidance about the expectations of the NRC.

A. The Supplementary information for the current rule includes the following statement:

> We recognize that physicians in training will not dedicate all of their time specifically to the subject areas in § 35.290(c)(1)(ii) and will be attending to other clinical matters involving the diagnostic use of the material under the supervision of an AU (e.g., reviewing case histories or interpreting scans). Even though these clinical matters are not specifically required by the NRC, this type of supervised work experience may be counted toward the supervised work experience to obtain the required 700 hours. [67 FR 20263 at page 20263]

B. In response to the comments raised by Agreement States relating to the "hours issue," the Supplementary information would include a revision to a statement in the current rule:

> In order to ensure the safe, medical use of byproduct materials, the NRC includes requirements in its regulations for training and experience in basic radionuclide handling technique applicable to the medical use of unsealed byproduct materials. For the alternate pathway, the NRC provides requirements for the training of nuclear pharmacists in radiation safety applicable to the medical use of byproduct material in § 35.55(b)(1); in the final rule, this includes a requirement for 200 hours of classroom and laboratory training. § 35.190(c)(1) requires that individuals must complete 60 hours of this training to become an authorized user of byproduct material for uses under § 35.100; this includes, in the final rule, a requirement for 8 hours of classroom and laboratory training. In § 35.290(c)(1), 700 hours of this training is required to become an authorized user of byproduct material for uses under § 35.200; in the final rule, this includes a requirement for 80 hours of classroom and laboratory training. In § 35.390(b)(1), 700 hours of this training is required to become an authorized user of byproduct material for uses under § 35.300; in the final rule, this includes a requirement for 200 hours of classroom and laboratory training. The added requirements, specifying a minimum number of hours of classroom and laboratory training were not added to the requirements for recognition of specialty board certifications because the NRC believes that it is important to provide flexible options for boards to evaluate the adequacy of T&E related to radiation safety. This flexibility is provided by a combination of evaluation through examinations, and academic and practical T&E. The NRC also recognizes that pharmacists and physicians in training will not dedicate all of their time specifically to the subject areas discussed in §§ 35.55(b)(1)(ii), 35.190(c)(1)(ii), 35.290(c)(1)(ii) and 35.390(b)(1)(ii) and will be attending to other clinical matters involving the medical use of the material. As part of their application for recognition of certifications, boards will be asked to provide information on how their examination process assesses the candidates knowledge related to radiation safety as it pertains to the subject areas enumerated in the regulations.

Attachment 4
Suggested Language for Implementation Procedures

Implementation procedures would be revised to add instructions to boards to submit information during their applications to enable evaluation of the adequacy of examinations as regards meeting requirements in revised regulations.

Revised procedures for implementation, listing, delisting procedures are as follows:

(This is based on the current draft procedures, Item 1, "Applications for Recognition of Specialty Board Certifications.)

> A specialty board requesting recognition should provide, via letter, a list of sections in Part 35 for which the board wishes to have its certification process(es) recognized. The letter should include a clear description of the board's requirements for certification and a statement that candidates for certification must complete the requirements for training and experience required by the section(s) applicable to the type of certification, for which the board is seeking recognition, prior to receiving board certification. The letter should provide information explaining how examinations administered by the board assesses competency in radiation safety. Sample topics and areas of coverage appear in §§ 35.50(b)(1), 35.55(b), 35.190(c) . . .. The letter of application should be dated and signed by the chief executive officer of the board, or designee. If the specialty board posts its requirements for certification on the World Wide Web, the board should also provide the web site designation (URL). The board should indicate when the certification program being described for recognition was established, i.e., became effective. (Diplomates of the board who, prior to recognition of the board, met the requirements of the program described for recognition can be considered for approval as AMPs, ANPs, AUs, or RSOs via the board certification pathway.) The board should also specify the length of time for which a certification is valid.

Attachment 5
Relative Merits of Specifying Minimal Hours for Alternative Pathway Only

Pros:

- Would ensure degree of consistency in training for individuals pursuing the alternate pathway.
- Helps with design of training programs by clarifying requirements of what is acceptable training.
- Provides clearer and more consistent criteria for reviewers of applications for licenses and amendments.
- Assures that the classroom and laboratory portion of training programs are not "watered down."
- Assures adequate amount of didactic training is provided to supplement the supervised clinical experience.
- Removes vagueness from regulation regarding requirements.
- Is receptive to the needs of the Agreement States, who must determine adequacy of didactic training programs
- Helps Agreement States maintain Compatibility B status of rule by clarifying requirements.
- Increases consistency between Agreement States and between the NRC and Agreement States.
- Boards are more likely to meet revised requirements - consistent with approach taken during development of the proposed rule.
- Allows boards more flexibility in design of training requirements.
- More in-line with recommendations of some members of the ACMUI subcommittee on T&E.

Cons:

- Increases prescriptiveness of regulations, counter to the aim of the Commission to use performance-based approach.
- Decreases flexibility to design training programs.
- Assessment of 'hours' difficult: an hour of on-line training not same as an hour of classroom training (ACMUI).
- Long time to implement may lengthen period of instability in regulation of medical use of byproduct materials.
- No need to revisit an issue already addressed in rulemaking for current regulations (ACMUI: "turning back the clock").
- "Clocking" a specific number of hours is no guarantee of mastery of subject (ACMUI).
- 3-year rulemaking would be required if the issue is not addressed in guidance space [rather than in regulation] (ACMUI - this argument may have been made with the assumption that requirement would apply to boards)
- Might not satisfy Agreement States if they wish to apply requirements to both the board certification and alternate pathways.
- It is difficult to defend prescriptive didactic hours for 35.190 and 35.290 based on risk, performance, and potential benefit.

Attachment 6
Dissent of Colleen Casey

I cannot accept Option 5 because I do not believe that the added burden, which would be substantial, justifies the risks posed by the practitioners in the affected modalities. I believe that the nuclear medicine and related industries have "matured" to the point where safety is ensured through the training pathways employed in the current rule, i.e., specialty board certifications and alternate pathway/preceptor training. The current rule is most consistent with a risk-informed and performance - based regulatory philosophy. To me, it seems to be in the best interest of "rulemaking economy," to continue an existing, familiar rule than to "reinvent the wheel."

No health and safety basis has been demonstrated that justifies restoring prescriptive didactic hours of Authorized User training. If nothing is broken, let's not "fix" it until it becomes broken, which is what Option 5 will do.

I also believe that NRC should adhere to the goals, strategies and means outlined and described in its Strategic Plan FY 2004 - 2009, especially the goals of safety, openness and effectiveness, as pertains to this matter. If Option 5 is adopted by the Steering Group (SG) and if this change in proposed rulemaking is not re-noticed for public comment, I believe NRC will not be supporting the tenets in the Strategic Plan.

However, it is not a "one size fits all world."

Therefore, my first choice would be to maintain the "status quo" by retaining the current rule and including the indefinite extension of Subpart J. This would accommodate the needs of NRC states' Authorized Users in the current rule and accommodate the Agreement States' (The States) concerns with prescriptive didactic hours of training in Subpart J. Having parallel rules has not proven to be a problem in the two years of NRC's implementation of new Part 35 so far.

My second choice would be to retain the current rule and implement the proposed rule without restoring prescriptive didactic Authorized User training hours. The States can adjust, as the NRC's regional offices have, and The States can accept other States' Authorized Users via reciprocity.

If one (or more) State chooses to not recognize Authorized Users named to an NRC or other State's license, then that state has created its own problem and it is not NRC's problem to fix. NRC's Authorized User applicants should not have to "pay" for a problem created and perpetuated by one or more Agreement States. The States should accept NRC- licensed and other Agreement State- licensed Authorized Users through reciprocity or an equivalent mechanism, as NRC accepts all Agreement State - licensed Authorized Users.

My third choice would be to modify option five but to reduce the number of prescriptive didactic hours of training in 10 CFR 35.290 from 80 to 40 and in 10 CFR 35.390 from 200 to 80 (the number of didactic hours in old Part 35 effective April 1, 1987 - April 24, 2002.)

The modified proposed rule should also be re-noticed for public comment because restoring prescriptive didactic training hours was not an obvious element in the proposed rule and the

stakeholders who will be affected by this change have not had an opportunity to comment. I could “live with” option five modified in this manner, if I had to.

Finally, if the Steering Group does select option five and move forward, consideration should be given to implementation for those physicians who are or will be in alternate pathway training, until the proposed rule becomes final, as this training can be used to support an application to become an Authorized User for up to seven years preceding the future date of application. This could generate confusion for everyone concerned.

Attachment 7
Dissent of Roger W. Broseus

A specification for a minimum number of hours of didactic [5] T&E should not be included in §§ 35.55, 35.190, 35.290, and 35.390 – the approach taken in draft-final rule before formation of the SG. The current regulations do not include such requirements and NRC staff reports that this is not an issue in licensing under current regulations. This issue was considered when the current regulations on T&E were published in revised Part 35 (April 2002), and the reasoning still holds: a more flexible, risk-informed, performance-based approach to the regulation of byproduct materials is in order, as directed by the Commission in its instructions to staff. The need to provide flexibility was recognized in the Supplementary Information for the current rule, in which it was also noted that useful, safety-related T&E is gained during the work experience of clinicians and others during their training programs. It is sufficient to have more prescriptive requirements in those sections of Part 35 for which risks are greater. It also would be useful to clarify, in guidance and the Supplementary Information for the final rule, the NRC's expectations for content of T&E (a more general statement could even be made that applications for licensure will be evaluated in a manner that ensures that "lip-service" is not being paid to requirements).

The NRC and Agreement State staff continually monitor medical events and other measures of performance to determine if action is needed, in guidance or in regulation. The pursuit of a performance-based, risk-informed philosophy should be given time to work unless an evaluation of indices of safety indicates otherwise. Imposition of more prescriptive requirements should not be attempted without additional input from the public on this important issue, which appeared to have been closed when current regulations were published in April 2002.

Specifying a minimum number of hours of didactic T&E in guidance – Option 1 – is not acceptable for Part 35 – much effort has been put into regulating through rules and not through guidance and adoption of this Option 1 would be counter to that effort. Option 2 (clarifying requirements for didactic T&E through revision of the preceptor statement) is unworkable because it would not satisfy AS concerns and could result in varying applications of the rules because of subjective interpretation by individual preceptors. The criticisms offered in the first two paragraphs of this dissent apply to Options 4, 5, and 6, with the added "con" for Option 4 (specifying didactic hours of T&E for both pathways) that, when applied to recognition of board certifications, the purpose of the rulemaking – to revise criteria for recognition of board certifications – could be undermined if boards do not now require a minimum number of hours of didactic T&E. Option 3 (exams) is unworkable because it is too logistically complex to implement, would take too long to implement, and is too costly, both for regulators and for stakeholders that would be subject to the requirement.

The least objectionable option which would include a specification for minimum number of hours is Option 6 because some may argue that, based on risk, the individuals serving as AUs for uses for which a WD is required should be required to have a minimum number of hours of

---

[5] "Didactic" is taken to refer to the "classroom and laboratory training" required to qualify as AUs as well as the didactic training required to qualify as an ANP in 35.55(b)(1)(i).

didactic T&E in safety related topics. However, the burden on affected stakeholders can not be assessed without additional input from the public.

It is not necessary to include a requirement for didactic T&E for ANPs because their programs are very rigorous and much of the safety-related T&E is gained in the experiential parts of their training programs.

Consistency and Compatibility: AS argue that they can not maintain Compatibility B status without a specification for a minimum number of hours of T&E. However, there are many areas in the regulations wherein prescriptiveness has been avoided without leading to AS having difficulty maintaining Compatibility B status for their regulations. NRC staff have determined, through experience, that applications can be evaluated without a specification for didactic hours of T&E, implying this is also possible for AS without inconsistencies arising. Further, some AS have already adopted the current regulations in Part 35 and we are unaware of them having problems with maintaining Compatibility B status.

If the SG determines that the final rule should go forward to the Commission with a specification in regulations for a minimum number of hours of didactic T&E in regulations, and the rule is not re-published for public comment, consideration should be given to presenting options to the Commission: a rule with and without a specification for hours of didactic T&E.