

Questions to ACMUI Subcommittee on T&E, July 7, 2004

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Compilation of Responses from Subcommittee
(extracted from attachments to emails)

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Email from Dr. Cerqueira, Chair, ACMUI

Question for the ACMUI: On what basis can radiation safety be assured for uses under §§ 35.100, 35.200, and 35.300 without a requirement for a minimum number of hours of didactic training in basic radionuclide handling techniques for Authorized Users (AUs) and for Authorized Nuclear Pharmacists (ANPs)?

Background: The NRC staff is seeking input from the ACMUI's subcommittee on T&E to assist in resolution of comments received on the proposed rule to revise requirements for training and experience in 10 CFR Part 35 (published for public comment on December 9, 2003 (68 FR 68549)). Some commenters were concerned that the lack of a specification for a minimal number of hours of didactic (class room and laboratory) training in basic radionuclide handling techniques applicable to Authorized Users (AUs) for uses under §§ 35.100, 35.200, and 35.300 and for authorized nuclear pharmacists (ANPs) could jeopardize radiation safety. The current requirements for T&E in radionuclide handling appear in the accompanying table along with example recommendations for a minimum number of hours of didactic training.

Section	Aggregate Requirement (hr)	Minimum Didactic Advocated
35.55	700*	200
35.190	60	8
35.290	700	80 to 100
35.390	700	200

* in a structured educational program, didactic & supervised experience.

Commenters from Agreement States advocated for requiring a minimum number of hours of didactic training to ensure radiation safety as well as for consistency of requirements, among Agreement States and between States and the NRC. While Agreement States must adopt the criteria for the total number of hours of training in radionuclide handling techniques, they might use criteria for evaluation of the minimum number of hours of didactic training when reviewing a license application or amendment, and these criteria could vary from State to State. This would likely result in inconsistencies between States in criteria for determining the adequacy of radiological safety training. In support of adding requirements for a minimum number of hours of didactic training, some ask, rhetorically, of the 700 hours required under, e.g., § 35.390, is one hour of didactic training sufficient? Five hours? To which the answer would (obviously) be, there must be some lower limit that a State would consider to be the minimum number that would be an adequate amount of didactic training. The issue of how to evaluate the adequacy of T&E takes on added significance because most license applications and evaluations will be performed in Agreement States (most licensees are located in Agreement States)

To resolve these issues, the Working Group (WG) for the rulemaking, under the guidance of a Steering Group, is charged with resolving the issues raised above and seeks input from the Subcommittee on T&E to assist with this task. The WG recognizes that these issues were discussed during development of the current regulations, published on April 24, 2002 (67 FR 20249) and during the proposed rule leading thereto. However, the issues continue to be of concern to AS, where the greatest majority of medical licensees exist and NRC management shares the concern, necessitating re-consideration.

Framing the Issue: The issue may be re-framed with emphasis on radiation safety: how should the NRC evaluate the adequacy of T&E to ensure radiation safety. Consider the following:

- 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. What is needed to ensure the safe medical use of byproduct material?

Possible Approaches to Resolving the Issue: The WG suggests that the Subcommittee focus on the following when providing feedback to help resolve the issues under discussion (this listing is meant as an aid and is not necessarily all-inclusive):

1. How can the NRC ensure adequacy of T&E in training in basic radionuclide handling techniques - with radiation safety being the measure. Note that AUs and ANPs may serve as RSOs, a consideration relevant to ensuring adequacy of radiation safety.
2. Examinations (existing 'models:' exams are now in use for approval of industrial radiographers using byproduct material and in one State for fluoroscopists and radiographers):
 - a. How could the assessment mentioned in item1 be made using an examination?
 - b. Who should administer the exam? The NRC? Agreement States? Other entities?
 - c. Should an exam be used for all classes of approvals, i.e., for RSOs, AMPs, and AUs?
 - d. If instituted, how much time should be allocated to implement the requirement?
3. Clarify the requirements in preceptor statements by requiring inclusion of an evaluation of the adequacy of didactic training in §§ 35.55, 35.190, 35.290 and 35.390.
4. What are the pros and cons of specifying a minimum number of hours of didactic training in basic radionuclide handling techniques?
5. If a requirement for a minimum number of hours of didactic training in basic radionuclide handling techniques is added to the requirements for T&E,
 - a. How can this be done, consistent with the objective of resolving problems (in the current regulations) with the requirements for recognition of specialty board certifications?
 - b. What would the minimum requirements be for §§ 35.55, 35.190, 35.290 and 35.390 such that boards would be likely to meet revised requirements.
 - c. Would they be better specified as a minimum number of hours or as percentages of total hours of T&E in handling techniques?
6. Could the objectives of ensuring safety, and consistency of requirements among Agreement States and between Agreement States and the NRC, be satisfied in guidance rather than in regulations? In the Statements of Consideration for the current regulations, the following statement appears:

“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.”

What statement would be a good substitute for this that would apply to §§ 35.55, 35.190, 35.290, and/or 35.390, thereby clarifying requirements for T&E as they relate to ensuring radiation safety?

7. Could the concern be dealt with in another manner? If so, describe it.

[Cerqueira's Comments]

Question for the ACMUI: On what basis can radiation safety be assured for uses under §§ 35.100, 35.200, and 35.300 without a requirement for a minimum number of hours of didactic training in basic radionuclide handling techniques for Authorized Users (AUs) and for Authorized Nuclear Pharmacists (ANPs)?

Background: The NRC staff is seeking input from the ACMUI's subcommittee on T&E to assist in resolution of comments received on the proposed rule to revise requirements for training and experience in 10 CFR Part 35 (published for public comment on December 9, 2003 (68 FR 68549)). Some commenters were concerned that the lack of a specification for a minimal number of hours of didactic (class room and laboratory) training in basic radionuclide handling techniques applicable to Authorized Users (AUs) for uses under §§ 35.100, 35.200, and 35.300 and for authorized nuclear pharmacists (ANPs) could jeopardize radiation safety. The current requirements for T&E in radionuclide handling appear in the accompanying table along with example recommendations for a minimum number of hours of didactic training.

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Possible Approaches to Resolving the Issue: The WG suggests that the Subcommittee focus on the following when providing feedback to help resolve the issues under discussion (this listing is meant as an aid and is not necessarily all-inclusive):

1. How can the NRC ensure adequacy of T&E in training in basic radionuclide handling techniques - with radiation safety being the measure. Note that AUs and ANPs may serve as RSOs, a consideration relevant to ensuring adequacy of radiation safety. [MDC The original intent of the revision of Part 35 was to make the process risk informed and performance based. We had originally included a reduced number of hours for classroom and didactic training, but after public comments in 3 regions of the country and input from the SNM and ACR, it was decided to eliminate specific hourly requirements for these areas and include only total training time. Especially in the area of diagnostics, it was felt that the risks were sufficiently low that proscriptive requirements were not necessary. This was to be monitored once the rule was enacted. I do not believe that in the nearly 2 years that the new rule has been in effect, there has been a problem. On many occasions it was pointed out that much more harm can be done by inappropriate administration of medications and performance of invasive diagnostic procedures and there are no hourly requirements placed on these areas. These areas were covered by the practice of medicine at the hospital credentialing and privileging committees and by professional medical societies and it was not the role of the NRC to get involved directly in the practice of medicine.]

2. Examinations (existing 'models:' exams are now in use for approval of industrial radiographers using byproduct material and in one State for fluoroscopists and radiographers): [MDC The original drafts had included an examination in radiation safety to be given by the NRC. When the cost and time for developing a credible examination were determined, the tremendous budgetary requirements made this cost prohibitive. In addition, it was felt that such a narrow focus on just the technical aspects of radiation safety did not assess the potential for adverse outcome in a clinical medical situation.]
 - a. How could the assessment mentioned in item be made using an examination? [Many of the boards already include technical questions on radiation safety but address the broader questions of patient management in the case of AU.]
 - b. Who should administer the exam? The NRC? Agreement States? Other entities? [The NRC and AS do not have expertise in this area-either the medical or the psychometric process of test development and administration]
 - c. Should an exam be used for all classes of approvals, i.e., for RSOs, AMPs, and AUs? [It should not be used for any of these groups.]
 - d. If instituted, how much time should be allocated to implement the requirement? [The NRC needs to stay out of this area. This involves the practice of medicine and a performance based evaluation will not find problems.]

3. Clarify the requirements in preceptor statements by requiring inclusion of an evaluation of the adequacy of didactic training in §§ 35.55, 35.190, 35.290 and 35.390. [The point has been made multiple times that very few will be able to attest to the competency of an individual. In no other area of medicine are preceptorships or training program directors expected to certify that some is competent.]

4. What are the pros and cons of specifying a minimum number of hours of didactic training in basic radionuclide handling techniques? [It is not necessary to micromanage the educational process to this extent. It is not done in any other areas of education or medicine. It should be left up to training programs and to boards to define the curriculum and let them fit it in in the best way possible.]

5. If a requirement for a minimum number of hours of didactic training in basic radionuclide handling techniques is added to the requirements for T&E,
 - a. How can this be done, consistent with the objective of resolving problems (in the current regulations) with the requirements for recognition of specialty board certifications? [This is not necessary to safeguard patients, radiation workers or the public and will be mandated by the majority of Boards. It is not the role of the NRC or the Agreement states to impose such restrictions unless a problem exists. Over the course of 5 years of discussions, for diagnostics, insufficient problems were identified.]
 - b. What would the minimum requirements be for §§ 35.55, 35.190, 35.290 and 35.390 such that boards would be likely to meet revised requirements. [During multiple presentations by the Boards, they did not seem willing to offer up this information. I do not think anything has changed.]
 - c. Would they be better specified as a minimum number of hours or as percentages of total hours of T&E in handling techniques? [The NRC and AS should not be involved in these matters unless there is a problem.]

6. Could the objectives of ensuring safety, and consistency of requirements among Agreement States and between Agreement States and the NRC, be satisfied in guidance rather than in regulations? In the Statements of Consideration for the current regulations, the following statement appears:

"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."

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What statement would be a good substitute for this that would apply to §§ 35.55, 35.190, 35.290, and/or 35.390, thereby clarifying requirements for T&E as they relate to ensuring radiation safety? I think this statement is a perfectly good statement that should be incorporated into the practices of the training programs. The NRC should stay out of this area. The NRC should not impose these restrictions in regulations. Many of the professional medical societies and Boards have developed or are developing a core program in classroom and didactic material to meet the standards they feel must be addressed. In Guidance documents, this material is handled more effectively.

7. Could the concern be dealt with in another manner? If so, describe it. Do not impose hours in the regulations. Make the agreement states be totally compliant with the NRC in T and E.

From: David Diamond <dagdmail@yahoo.com>
To: Jeff Williamson <jfwilliamson@vcu.edu>, Ruth McBurney <ruth.mcburney@tdh.state.tx.us>, Angela Williamson <arw@nrc.gov>, Richard Vetter <richard.vetter@mayo.edu>, Manuel Cerqueira <cerqm@concentric.net>, <deggli@psu.edu>
Date: 7/12/04 9:30AM
Subject: Working Group Response

Dear Fellow Sub-committee Members:

I welcome the opportunity to comment on the NRC Working Group's "talking points and questions" of 7/7/04, raised at behest of several Agreement State representatives.

Although I appreciate the concerns raised by some of the State representatives that the absence of an enumerated breakdown of training and didactic hours in the subparts in question (35.100-300 uses) in the current rule may cause some inconsistencies among states in criteria for determining the adequacy of radiological safety training, I believe this would best be resolved in guidance space. I understand several of my colleagues in the ACMUI share this feeling.

As I "frame the issue", I believe it vital that we recall that over the last several years of rule-making we in the ACMUI have endeavored to pursue risk-based, less prescriptive regulation that recognizes the vital role of the specialty boards and encourages individuals to pursue a board-certification pathway. The general thrust of recommendations raised in the memo could easily contravene these principles.

We have also attempted to consider the cost and burden of our mandates. In this regard, I believe an attempt to develop new, high quality examinations (either through the NRC or a private contractor) for the few who elect to pursue the "alternate pathway" for AU or ANP status (and in the absence of reason to believe that public safety would be impaired) would be extremely laborious and a very poor return on governmental resources.

Thank you,

David Diamond, MD

CC: <rez@nrc.gov>, <rjt@nrc.gov>, <rwb@nrc.gov>, <slw1@nrc.gov>, <swm@nrc.gov>

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Possible Approaches to Resolving the Issue: The WG suggests that the Subcommittee focus on the following when providing feedback to help resolve the issues under discussion (this listing is meant as an aid and is not necessarily all-inclusive):

General Comments:

The move toward a more prescriptive regulation is a big step backward, away from risk informed/performance based regulation.

As an AU trying to design a didactic program, combining didactic lectures with laboratory experience in the hours requirement makes it very difficult to design a program that will meet everyone's interpretation of an adequate program. If there is going to be a specific time requirement, it would be far more helpful to have the requirement for didactic lecture separated from the "laboratory experience", which is more practical rather than didactic. When we think about didactic education in academic medicine, it means formal lectures. Laboratory experience is a different category of education, more like practical experience.

(Note that 35.55 does separate didactic from laboratory/practical experience while 35.190, 35.290, and 35.390 do not.)

The minimum number of didactic hours (lecture only, excluding practical and laboratory experience) advocated above is excessive. In the "old" Part 35, a total of two hundred classroom/didactic hours were required. This is well in excess of the knowledge base required for safe handling of radioactive materials. A total number of classroom/didactic lecture hours in the range of 60 to 70 hours for parts 35.290 and 35.390 should be fully adequate to impart the "core knowledge" required in c.1.i.a through c.1.i.e for 35.290 and b.1.i.a through b.1.i.e for part 35.390. (This does not include laboratory and practical experience).

The "core didactic knowledge" for safe handling of radioactive materials is the same whether the practitioner works in 35.190, 35.290, or 35.390. There may be a different core knowledge requirement for a radiopharmacist/radiochemist in 35.55, who handles radioactive materials more extensively than clinical practitioners. (Sally should have the opportunity to address this issue).

1. How can the NRC ensure adequacy of T&E in training in basic radionuclide handling techniques - with radiation safety being the measure. Note that AUs and ANPs may serve as RSOs, a consideration relevant to ensuring adequacy of radiation safety.

An AU who wants to serve an AMP or RSO should be required to demonstrate experience and mastery of the appropriate body of knowledge required by the position. An AU should not be allowed to be an AMP or RSO simply as a function of AU status. This would impose a significant and unnecessary training burden on the vast majority of AUs who never intend to function as AMPs or RSOs.

The NRC should insure the adequacy of didactic training the same way it insures the adequacy of any training, which is via a preceptor statement and supporting documentation.

2. Examinations (existing 'models:' exams are now in use for approval of industrial radiographers using byproduct material and in one State for fluoroscopists and radiographers):
 - a. How could the assessment mentioned in item be made using an examination?

Creating an examination is a nontrivial process.

A large group of questions representing each of the subject areas (eg: radiation biology, radiation safety, radiopharmacy, instrumentation, mathematics of radiation calculations, etc) has to be developed. Any individual exam has to be drawn from this pool of "vetted" questions such that the subject material is adequately represented. Every time the exam is given, it should be similar in scope and difficulty to prior exams, but not repetitive enough that simply studying answers to prior tests can result in a passing grade. This generally requires the exam to be reviewed by psychometricians.

This process is probably best performed by the various certifying boards, which have the necessary expertise in testing. I do not believe that either NRC or the Agreement States have this expertise.

- b. Who should administer the exam? The NRC? Agreement States? Other entities?

The certifying boards could be asked to separately score the relevant questions on their certifying exam and to report that score to the candidate. A copy of the score for the questions relevant to radiation safety could be provided with the preceptor statement.

Alternatively each training program could administer its own exam on radiation safety and the preceptor could attest to the "mastery of a body of radiation safety knowledge". This is what we had planned to do for our program. The preceptor already shoulders a significant responsibility precepting a candidate, attesting to the mastery of a specific body of didactic knowledge is not significantly different from what the preceptor is already being asked to attest to.

I do not think that Agreement States or the NRC should administer such an exam.

- c. Should an exam be used for all classes of approvals, i.e., for RSOs, AMPs, and AUs?

If an exam is to be used, it seems appropriate that it would be used for all categories of users. The exam, however, should be tailored to the specific functions performed by each group of users. An RSO and AU should have a different exam. If an AU wants to function as an RSO, then the AU would need to pass the RSO exam as well as the AU exam.

- d. If instituted, how much time should be allocated to implement the requirement?

If the certifying boards take on the task, it would take at least 2 years for them to gear up. If individual training programs take on the task, the time could be shorter. One year would probably be enough time.

3. Clarify the requirements in preceptor statements by requiring inclusion of an evaluation of the adequacy of didactic training in §§ 35.55, 35.190, 35.290 and 35.390.

This would be an easy addition to the preceptor statement. I think this would be the preferred method of attesting to the didactic training. The attestation could include a statement of the training provided, and if an examination was given, the preceptor could additionally attest to the mastery of a body of knowledge.

4. What are the pros and cons of specifying a minimum number of hours of didactic training in basic radionuclide handling techniques?

CONs:

"Clocking" a specific number of hours is no guarantee of mastery of the subject
Limited flexibility is available in teaching the material
Still would require some demonstration of mastery of the material.

PROs:

Consistency of requirement for licensure from state to state

5. If a requirement for a minimum number of hours of didactic training in basic radionuclide handling techniques is added to the requirements for T&E,

- a. How can this be done, consistent with the objective of resolving problems (in the current regulations) with the requirements for recognition of specialty board certifications?

The requirement for a specific number of hours will complicate the requirement for recognition of the specialty certifying boards. The boards tend to resist detailed subject matter mandates. A prescriptive requirement for training runs contrary to NRC's move toward more performance based regulations.

The Agreement States are asking the NRC to turn back the clock.

- b. What would the minimum requirements be for §§ 35.55, 35.190, 35.290 and 35.390 such that boards would be likely to meet revised requirements.

I think that asking the preceptor to attest to the candidates mastery of the didactic knowledge areas specified in the regulation would be the minimum requirement and the one most likely to be acceptable to the specialty certifying boards.

Asking the specialty boards to separately score the sections of their certifying examination relevant to safe handling of radioactive materials is reasonable. Although I think the specialty certifying boards may initially resist this requirement, I think they would ultimately agree.

Specifying a curriculum (including total hours) that the boards and programs must incorporate would be least acceptable.

If hours are specified, I would separate the didactic/lecture requirement from the practical/laboratory training requirement, to improve clarity.

- c. Would they be better specified as a minimum number of hours or as percentages of total hours of T&E in handling techniques?

I would specify a number of hours rather than a percentage of required time. If total T&E were ever to expand or contract, the didactic component would be unaffected if hours are specified.

6. Could the objectives of ensuring safety, and consistency of requirements among Agreement States and between Agreement States and the NRC, be satisfied in guidance rather than in regulations? In the Statements of Consideration for the current regulations, the following statement appears:

“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.”

The comment above is appropriate for “guidance”. For the T & E requirements, the guidance would need to be specific enough that there would be no confusion as to the requirements. The problem is that you can’t be just a little bit prescriptive. If you intend to make a prescriptive T&E rule, it needs to be detailed enough to avoid confusion and inconsistent application.

Also, I think the specialty certification boards will be more reluctant to incorporate changes into their programs if the requirements exist in “guidance space” alone. The boards will want something that they perceive will be stable for several years and less subject to short notice change,

What statement would be a good substitute for this that would apply to §§ 35.55, 35.190, 35.290, and/or 35.390, thereby clarifying requirements for T&E as they relate to ensuring radiation safety?

Again, I am not sure that the specialty certification boards will want to see the time requirement for didactic education specified in guidance space, but if they agree wording could be as follows:

“A didactic curriculum meeting the requirement of parts 35.55(b)(1)(i), 35.190(c)(1)(i), 35.290(c)(1)(i), and 35.390(b)(1)(i) would contain between 60 and 70 hours of classroom lectures.”

7. Could the concern be dealt with in another manner? If so, describe it.

Options are limited. The concerns of the Agreement States have to be addressed, but should be addressed within the general outline of risk informed/performance based regulation.

I would propose a three-part solution:

1. Require the preceptor to attest to the candidate's mastery of a core of knowledge relevant to the safe handling of radioactive materials.
2. Ask the specialty certifying boards to separately score and report to the candidate their score on the portions of the certifying examination relevant to safe handling of radioactive materials.
3. Require the candidate to submit proof of a passing score on the relevant portion of their certifying exam along with their preceptor statement when requesting licensure.

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Commenters from Agreement States advocated for requiring a minimum number of hours of didactic training to ensure radiation safety as well as for consistency of requirements, among Agreement States and between States and the NRC. While Agreement States must adopt the criteria for the total number of hours of training in radionuclide handling techniques, they might use criteria for evaluation of the minimum number of hours of didactic training when reviewing a license application or amendment, and these criteria could vary from State to State. This would likely result in inconsistencies between States in criteria for determining the adequacy of radiological safety training. In support of adding requirements for a minimum number of hours of didactic training, some ask, rhetorically, of the 700 hours required under, e.g., § 35.390, is one hour of didactic training sufficient? Five hours? To which the answer would (obviously) be, there must be some lower limit that a State would consider to be the minimum number that would be an adequate amount of didactic training. The issue of how to evaluate the adequacy of T&E takes on added significance because most license applications and evaluations will be performed in Agreement States (most licensees are located in Agreement States)

To resolve these issues, the Working Group (WG) for the rulemaking, under the guidance of a Steering Group, is charged with resolving the issues raised above and seeks input from the Subcommittee on T&E to assist with this task. The WG recognizes that these issues were discussed during development of the current regulations, published on April 24, 2002 (67 FR 20249) and during the proposed rule leading thereto. However, the issues continue to be of concern to AS, where the greatest majority of medical licensees exist and NRC management shares the concern, necessitating re-consideration.

Framing the Issue: The issue may be re-framed with emphasis on radiation safety: how should the NRC evaluate the adequacy of T&E to ensure radiation safety. Consider the following:

- 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. What is needed to ensure the safe medical use of byproduct material?

Possible Approaches to Resolving the Issue: The WG suggests that the Subcommittee focus on the following when providing feedback to help resolve the issues under discussion (this listing is meant as an aid and is not necessarily all-inclusive):

1. How can the NRC ensure adequacy of T&E in training in basic radionuclide handling techniques - with radiation safety being the measure. Note that AUs and ANPs may serve as RSOs, a consideration relevant to ensuring adequacy of radiation safety.

There are several possible ways to assure adequacy and maintain a uniform and consistent implementation of the rule—the first is to specify the portion of the total hours required that should be devoted to didactic training, either by rule or by guidance. If it is put into guidance, each regulatory agency will still be evaluating training programs to assure that the appropriate amount of attention is paid to radiation safety and radioisotope handling. Another method would be for an exam administered by NRC/Agreement States for the “alternate route” applicants, and assurance that Board exams cover the same level of radiation safety before approving the Boards. This option would be labor intensive for the regulatory agencies.

2. Examinations (existing ‘models:’ exams are now in use for approval of industrial radiographers using byproduct material and in one State for fluoroscopists and radiographers):

- a. How could the assessment mentioned in item 1 be made using an examination?

If an exam is used to assess the didactic training, it should focus on radiation safety issues and radioisotope handling techniques, whereas the supervised experience would concentrate on clinical use and interpretation of scans. If the Board exams include similar questions on radiation safety and isotope handling, the exams could be limited to only those applicants that fall under the “alternate route.”

- b. Who should administer the exam? The NRC? Agreement States? Other entities? Regulatory agencies or non-profit entities, such as ACR, could possibly administer the exams. As mentioned above, this option would be labor intensive for the regulatory agencies.

Coming from a state regulatory program that first implemented a radiation safety exam for industrial radiographers, the development of an item bank, testing of statistical validity, and developing and implementing associated rules and programs took several years to finalize. It might be possible to have other entities develop this as an accreditation for users and RSOs.

- c. Should an exam be used for all classes of approvals, i.e., for RSOs, AMPs, and AUs?

The primary question that has brought us to evaluating the issue of didactic training pertains primarily to authorized users and AUs that serve as RSOs. The training for AMPs and RSOs is more specific in the rule and is more uniformly applied already. Therefore, I think it should be limited to the AUs in §§ 35.55, 35.190, 35.290 and 35.390.

- d. If instituted, how much time should be allocated to implement the requirement?

3. Clarify the requirements in preceptor statements by requiring inclusion of an evaluation of the adequacy of didactic training in §§ 35.55, 35.190, 35.290 and 35.390.

This may not be possible when the didactic training and “hands-on” training and supervised experience are not received in the same location. In those cases, all the preceptor could do is affirm that the applicant “has received X hours classroom and laboratory training that included the topics in Section XXX” or similar information. The preceptor could only affirm this after reviewing the course content of the applicant or by knowing what was included.

4. What are the pros and cons of specifying a minimum number of hours of didactic training in basic radionuclide handling techniques?

Pros: If there are no guidelines or rules that specify a minimum number of hours necessary to adequately cover the basic principles in each section for safe handling of radioactive material, it is likely that training programs will become diluted. Specification of hours of training will better ensure adequate radiation safety training for AU's. It would also improve and ensure consistency and uniformity of training requirements.

Cons: The specificity would be more prescriptive than the current rule and go away from "performance based" standards. It would require rulemaking, which would take up to 3 more years to implement, unless it could be addressed in guidance.

5. If a requirement for a minimum number of hours of didactic training in basic radionuclide handling techniques is added to the requirements for T&E,

- a. How can this be done, consistent with the objective of resolving problems (in the current regulations) with the requirements for recognition of specialty board certifications?

If it could be ascertained that Board certification exams include testing on radiation safety and isotope handling, the number of hours didactic could only be applied to the "alternate route" applicants. The issue is that there be a mechanism in place to assure adequate training. Since Board certification includes an examination on the subject knowledge, that could be one mechanism, versus a specified number of hours for those applying under the alternate standards.

- b. What would the minimum requirements be for §§ 35.55, 35.190, 35.290 and 35.390 such that boards would be likely to meet revised requirements.

The aggregate requirement could stay the same for both, and be specified for the alternate standards route. If they are to be specified for both, the number of hours in the box above would be appropriate, except that a minimum of 16 hours should be listed for 35.190.

- c. Would they be better specified as a minimum number of hours or as percentages of total hours of T&E in handling techniques? Either; if expressed as a percentage, it should be somewhere in the range of 25%/75% to 33%/67%.

6. Could the objectives of ensuring safety, and consistency of requirements among Agreement States and between Agreement States and the NRC, be satisfied in guidance rather than in regulations? In the Statements of Consideration for the current regulations, the following statement appears:

"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."

What statement would be a good substitute for this that would apply to §§ 35.55, 35.190, 35.290, and/or 35.390, thereby clarifying requirements for T&E as they relate to ensuring radiation safety? This goes back to whether the preceptor can verify and affirm the amount of didactic training that was involved in the total number of aggregate hours. If

they can truthfully affirm and include number of hours in the preceptor statement and the course topics covered, it might be able to be achieved. The down side of this is the variety of interpretations and implementation issues across jurisdictions (NRC and Agreement States).

7. Could the concern be dealt with in another manner? If so, describe it.

It really needs to be addressed either through rulemaking or clear guidance in order to achieve some level of uniformity and consistency.

[Vetter's Comments]

Question for the ACMUI: On what basis can radiation safety be assured for uses under §§ 35.100, 35.200, and 35.300 without a requirement for a minimum number of hours of didactic training in basic radionuclide handling techniques for Authorized Users (AUs) and for Authorized Nuclear Pharmacists (ANPs)?

Background: The NRC staff is seeking input from the ACMUI's subcommittee on T&E to assist in resolution of comments received on the proposed rule to revise requirements for training and experience in 10 CFR Part 35 (published for public comment on December 9, 2003 (68 FR 68549)). Some commenters were concerned that the lack of a specification for a minimal number of hours of didactic (class room and laboratory) training in basic radionuclide handling techniques applicable to Authorized Users (AUs) for uses under §§ 35.100, 35.200, and 35.300 and for authorized nuclear pharmacists (ANPs) could jeopardize radiation safety. The current requirements for T&E in radionuclide handling appear in the accompanying table along with example recommendations for a minimum number of hours of didactic training.

Section	Aggregate Requirement (hr)	Minimum Didactic Advocated
35.55	700*	200
35.190	60	8
35.290	700	80 to 100
35.390	700	200

* in a structured educational program, didactic & supervised experience.

Commenters from Agreement States advocated for requiring a minimum number of hours of didactic training to ensure radiation safety as well as for consistency of requirements, among Agreement States and between States and the NRC. While Agreement States must adopt the criteria for the total number of hours of training in radionuclide handling techniques, they might use criteria for evaluation of the minimum number of hours of didactic training when reviewing a license application or amendment, and these criteria could vary from State to State. This would likely result in inconsistencies between States in criteria for determining the adequacy of radiological safety training. In support of adding requirements for a minimum number of hours of didactic training, some ask, rhetorically, of the 700 hours required under, e.g., § 35.390, is one hour of didactic training sufficient? Five hours? To which the answer would (obviously) be, there must be some lower limit that a State would consider to be the minimum number that would be an adequate amount of didactic training. The issue of how to evaluate the adequacy of T&E takes on added significance because most license applications and evaluations will be performed in Agreement States (most licensees are located in Agreement States)

To resolve these issues, the Working Group (WG) for the rulemaking, under the guidance of a Steering Group, is charged with resolving the issues raised above and seeks input from the Subcommittee on T&E to assist with this task. The WG recognizes that these issues were discussed during development of the current regulations, published on April 24, 2002 (67 FR 20249) and during the proposed rule leading thereto. However, the issues continue to be of concern to AS, where the greatest majority of medical licensees exist and NRC management shares the concern, necessitating re-consideration.

Framing the Issue: The issue may be re-framed with emphasis on radiation safety: how should the NRC evaluate the adequacy of T&E to ensure radiation safety. Consider the following:

- 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. What is needed to ensure the safe medical use of byproduct material?

Possible Approaches to Resolving the Issue: The WG suggests that the Subcommittee focus on the following when providing feedback to help resolve the issues under discussion (this listing is meant as an aid and is not necessarily all-inclusive):

1. How can the NRC ensure adequacy of T&E in training in basic radionuclide handling techniques - with radiation safety being the measure. Note that AUs and ANPs may serve as RSOs, a consideration relevant to ensuring adequacy of radiation safety. [RJVetter: Personally, I don't see the problem. The rules already specify that a certain number of hours of training and experience are required and that the T&E include radiation safety. There is tremendous pressure, especially in adult education, to move away from typical classroom training. Increasingly, education programs are incorporating on-line training into their curricula. One hour of on-line training of often much more productive than one hour of classroom training. Thus, hours are no longer a good measure. I think the NRC should allow people to learn the material any way they wish. The desired result isn't that the individual spent a certain number of hours in a classroom. Rather, the desired result is that they can work safely. If regulators want proof of knowledge, they need to institute an examination process. Of course, those who are certified by a specialty board have already passed an exam. However, where is the problem? Has compliance history demonstrated that there is a problem here?]
2. Examinations (existing 'models:' exams are now in use for approval of industrial radiographers using byproduct material and in one State for fluoroscopists and radiographers):
 - a. How could the assessment mentioned in item be made using an examination? [RJVetter: NRC has staff who are certified by the American Board of Health Physics, and at least one of them has participated in the leadership of the American Academy of Health Physics. They know how the process works and could write items for an exam that covers the appropriate material. I have served on both ABHP and ABMP, and I know how time consuming item writing is. So, if NRC moves to an exam, the process must have integrity, which will require considerable staff or contractor time.]
 - b. Who should administer the exam? The NRC? Agreement States? Other entities? [RJVetter: NRC or a contractor could administer the exam.]
 - c. Should an exam be used for all classes of approvals, i.e., for RSOs, AMPs, and AUs? [RJVetter: If an exam is used for one class of approval, it should be used for all. Of course, those individuals who are certified by a specialty board will have already passed an exam; therefore, they will have qualified through the Board Certification pathway. An exam requirement for those who are not board certified might even stimulate some people to go get their boards. Ultimately, such a stimulus would reduce NRC workload by increasing the number of applicants who are already board certified thus decreasing the number who wish to qualify through the NRC exam and alternate pathway. That would be a good thing.]
 - d. If instituted, how much time should be allocated to implement the requirement? [RJVetter: I don't know how to evaluate this question. It depends on how long it would take for NRC to develop the exam and the process to administer it.]
3. Clarify the requirements in preceptor statements by requiring inclusion of an evaluation of the adequacy of didactic training in §§ 35.55, 35.190, 35.290 and 35.390. [RJVetter: I think this would be a disaster. For example, if I hire a health physicist right out of college, I will serve as his/her preceptor while he/she gains experience and will sign a preceptor form for the experience. Who signs for the coursework - the person's college advisor? What would you expect that advisor to say other than the coursework is adequate? If an evaluation is required, what would that evaluation consist of?]
4. What are the pros and cons of specifying a minimum number of hours of didactic training in basic radionuclide handling techniques? [RJVetter: Pros - none. Con - NRC is getting too prescriptive; as I stated earlier, modern adult education is providing many alternatives to classroom training; many people can complete an on-line didactic session and absorb the material more quickly than can be accomplished in the classroom, thus an hour of one is not equivalent to an hour of the other.]
5. If a requirement for a minimum number of hours of didactic training in basic radionuclide handling techniques is added to the requirements for T&E,
 - a. How can this be done, consistent with the objective of resolving problems (in the current regulations) with the requirements for recognition of specialty board certifications? [RJVetter: this opens up a new can of worms that could result in considerable push back from specialty boards. They don't respond well to prescriptive regulations. They are focused on performance and professionalism, not training. Some boards may not care how the individual learned the material as long as they can pass the exam and work in a safe, professional manner.]
 - b. What would the minimum requirements be for §§ 35.55, 35.190, 35.290 and 35.390 such that boards would be likely to meet revised requirements. [RJVetter: you need to ask the boards]
 - c. Would they be better specified as a minimum number of hours or as percentages of total hours of T&E in handling techniques? [RJVetter: I don't think this would be any better than prescribing hours.]
6. Could the objectives of ensuring safety, and consistency of requirements among Agreement States and between Agreement States and the NRC, be satisfied in guidance rather than in regulations? In the Statements of Consideration for the current regulations, the following statement appears:

"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."

What statement would be a good substitute for this that would apply to §§ 35.55, 35.190, 35.290, and/or 35.390, thereby clarifying requirements for T&E as they relate to ensuring radiation safety? [RJVetter: Yes, I think the concerns expressed by Agreement States could be addressed in guidance space. You could consider adding something like the following to the above statement. "However, we expect the training to include appropriate radiation safety and radioisotope handling instructions that are adequate to assure that the physicians in training will be able to use radioisotopes in a safe manner and will know what to do and who to contact when a problem or emergency arises."]

7. Could the concern be dealt with in another manner? If so, describe it. [RJVetter: I really like addressing the concern in guidance space rather than making the T&E sections more prescriptive. The point I would like to emphasize strongly is that our (T&E Subcommittee) desire has been to encourage people to seek authorization through the board certification pathway. Exams are performance based, hours in a classroom are not. Also, people who become board certified are likely to remain connected with the professional community where they can learn from each other and are required to re-certify through an examination or continuing education. Thus, anything we can do to encourage that route, in my opinion, will have a more satisfactory long-term outcome.]

Williamson's Comments

Question for the ACMUI: On what basis can radiation safety be assured for uses under §§ 35.100, 35.200, and 35.300 without a requirement for a minimum number of hours of didactic training in basic radionuclide handling techniques for Authorized Users (AUs) and for Authorized Nuclear Pharmacists (ANPs)?

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- 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. What is needed to ensure the safe medical use of byproduct material?

Possible Approaches to Resolving the Issue: The WG suggests that the Subcommittee focus on the following when providing feedback to help resolve the issues under discussion (this listing is meant as an aid and is not necessarily all-inclusive):

1. How can the NRC ensure adequacy of T&E in training in basic radionuclide handling techniques - with radiation safety being the measure. Note that AUs and ANPs may serve as RSOs, a consideration relevant to ensuring adequacy of radiation safety.

What problem or threat to public safety concerns the ASs? I would make several observations

- (1) Under the old Part 35 and its current Subpart J extension there has been effectively no minimum hour requirement (either aggregate or didactic) for applicants passing through the board cert pathway. If one has board certification by one of the boards listed in the regulation, one gets to be an AU, ANP, or RSO. This system appears to have served the nation well. I ask the AS to justify, by showing data to demonstrate that we have a threat to safety before abandoning a well functioning industry standard.
- (2) The current Part 35 rule specifies 700 hours of training. What justification is there for making additional restrictions?
- (3) I think NRC should tell AS to get their heads out of the prescriptive/punative era and adopt the more performance based paradigm developed by NRC
- (4) At its last meeting, ACMUI unanimously backed dropping the 700 h requirement for 35.390 in favor a certification-exam based approach (requiring exam plus ACGME residency in radiology, nuc med, or Rad Onc) plus 12 cases of supervised experience. If this approach is abandoned to solely to "make life easy" for AS license reviewers who can't accept a more performance-based approach, patients will be denied access to radionuclide therapy by a well-qualified group of practitioners: radiation oncologists.

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2. Examinations (existing 'models:' exams are now in use for approval of industrial radiographers using byproduct material and in one State for fluoroscopists and radiographers):
 - a. How could the assessment mentioned in item be made using an examination?
 - b. Who should administer the exam? The NRC? Agreement States? Other entities?
 - c. Should an exam be used for all classes of approvals, i.e., for RSOs, AMPs, and AUs?
 - d. If instituted, how much time should be allocated to implement the requirement?

ACMUI discussed additional exams a long time ago. Both staff and ACMUI advocated dropping the additional safety exam from the straw man rule, a recommendation accepted by the Commission. To add an additional exam flies contrary to both common sense and the Commission's injunction to use industry standards (Board certification) where applicable. If NRC follows this path, it will be extraordinarily expensive, will do little to improve public safety, and could limit patient access to radiation medicine by increasing costs and limiting practitioners

3. Clarify the requirements in preceptor statements by requiring inclusion of an evaluation of the adequacy of didactic training in §§ 35.55, 35.190, 35.290 and 35.390.

This would be very difficult if not impossible to achieve. Applicants may receive their didactic from a variety of sources and could create an unreasonable and unclear burden for preceptors, who are concerned with practical performance, to evaluate all this material.
4. What are the pros and cons of specifying a minimum number of hours of didactic training in basic radionuclide handling techniques?

It
5. If a requirement for a minimum number of hours of didactic training in basic radionuclide handling techniques is added to the requirements for T&E,
 - a. How can this be done, consistent with the objective of resolving problems (in the current regulations) with the requirements for recognition of specialty board certifications?

There is a problem. In 35.400 and 35.600, hourly requirements exist only for alternative pathway. The certification pathway requires 3 years of ACGME residency, so NRC relies on this curriculum for adequacy of training. 35.390 is a cross-over area, in which both physicians from the diagnostic side (who have hour-based training criteria) and radiation oncologists (who have residency-based T&E) practice. Adding more restrictive hours of training requirements would increase the likelihood that radiation oncologists' ability to practice radionuclide therapy would be jeopardized.
 - b. What would the minimum requirements be for §§ 35.55, 35.190, 35.290 and 35.390 such that boards would be likely to meet revised requirements.
 - c. Would they be better specified as a minimum number of hours or as percentages of total hours of T&E in handling techniques?
6. Could the objectives of ensuring safety, and consistency of requirements among Agreement States and between Agreement States and the NRC, be satisfied in guidance rather than in regulations? In the Statements of Consideration for the current regulations, the following statement appears:

"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.”

What statement would be a good substitute for this that would apply to §§ 35.55, 35.190, 35.290, and/or 35.390, thereby clarifying requirements for T&E as they relate to ensuring radiation safety?

7. Could the concern be dealt with in another manner? If so, describe it.

I recommend staying with the approach last approved by ACMUI for 35.390 and leaving only an aggregate hourly training requirement for 35/100 and 200.

From: "Manuel Cerqueira" <cerqm@concentric.net>
To: "Thomas Essig" <THE@nrc.gov>, <SchwarzS@mir.wustl.edu>, <deggli@psu.edu>, <MALMUDLS@tuhs.temple.edu>, <dagdmail@yahoo.com>
Date: 6/8/04 5:28PM
Subject: RE: Summary of June 2 telecon re. Part 35 T&E

Tom,

I did not receive any notification regarding this conference call and the conclusions reached as reflected in your minutes are not acceptable to me. We had over 5 years of open and closed meetings addressing the T and E requirements and had originally listed hours for didactic and laboratory, but there was such an outcry from the regulated community that the final decision was to not specify hourly requirements. You cannot reverse 4-5 years of work with a single conference call to which the full committee was not invited to take part.

Please give me a call so we can discuss this issue. I never understood why NRC emails to the committee were not always sent to the entire committee. There are people on the committee not listed on the To line.

I have accepted a new position at the Cleveland Clinic starting on July 1, 2004. I will continue to use this email address. My new contact information follows:

Chairman
Department of Molecular and Functional Imaging (Gb3)
Cleveland Clinic Foundation
9500 Euclid Ave
Cleveland, OH 44195
Telephone 216-444-2665
Fax 216-444-3943
Email cerqm@concentric.net

Manuel D. Cerqueira MD
Professor of Medicine and Radiology
Chief of Cardiology
Director of Nuclear Cardiology & Exercise Laboratories
Georgetown University Medical Center
Division of Cardiology (5PHC)
3800 Reservoir Road NW
Washington DC 20007-2197

Email cerqm@concentric.net
Telephone 202-444-7190
Facsimile 202-444-4593

-----Original Message-----

From: Thomas Essig [mailto:THE@nrc.gov]
Sent: Monday, June 07, 2004 5:57 PM
To: cerqm@concentric.net; SchwarzS@mir.wustl.edu; deggli@psu.edu; MALMUDLS@tuhs.temple.edu; dagdmail@yahoo.com
Cc: Angela Williamson; Roberto Torres; Roger Broseus