RULEMAKING ISSUE
NOTATION VOTE

October 30, 2002 SECY-02-0194

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: OPTIONS FOR ADDRESSING PART 35 TRAINING AND EXPERIENCE ISSUES ASSOCIATED WITH RECOGNITION OF SPECIALTY BOARDS BY NRC

PURPOSE:

To present options for Commission consideration in resolving issues associated with the training and experience (T&E) requirements in the recently published final rule amending 10 CFR Part 35, as they apply to the recognition of specialty boards by NRC.

SUMMARY:

On April 12, 2002, the Commission issued a Staff Requirements Memorandum (SRM), in response to COMSECY-02-0014, that approved a final rule regarding "Medical Use of Byproduct Material." The final rule was published in the Federal Register on April 24, 2002 (67 FR 20250) and will become effective on October 24, 2002. In a supplemental SRM issued on April 16, 2002, the Commission directed the staff to "develop a SECY paper that discusses various options for addressing the T&E issue before the revised final rule becomes effective." This Commission paper presents three options for Commission consideration. Option 1 is to retain the existing requirements in the final rule. Option 2 is to prepare a proposed rule to modify T&E requirements based on the recommendations submitted by the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Option 3 is the same as Option 2 with a

CONTACT: Anthony Tse, NMSS/IMNS
(301) 415-6233

minor modification (i.e., listing all specialty boards recognized by NRC on the website rather than, as recommended by ACMUI, listing some boards in the regulation and others on the website). The staff recommends that the Commission adopt Option 3.

BACKGROUND:

The issue in question concerns the new requirements in the final rule governing the recognition of specialty boards (boards) by NRC. These requirements are in the final rule at 10 CFR 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590, and 35.690. The boards represent one of two alternative pathways for certifying authorized individuals (e.g., radiation safety officers (RSOs), authorized medical physicists (AMPs), authorized nuclear pharmacists (ANPs), and authorized users (AUs)). The other alternative is through evaluation of individual training and experience (T&E process).

During development of the Part 35 proposed and final rules, there was a general belief that the boards currently recognized by NRC would meet, or could make adjustments to meet, the new requirements and that they would continue to be recognized by NRC. However, when applications for recognition were received, the staff determined that, except for one board, the boards did not meet all the requirements specified in the final rule. Specifically, the boards' certification programs failed to meet the requirements in the final rule regarding preceptor certification and work experience. The only board that currently meets the revised requirements is the Certification Board of Nuclear Cardiology, because it developed its certification program based on the final rule. On various occasions, the staff discussed with the boards as to whether the boards would modify their certifying programs to meet all the requirements specified in the rule. No board indicated that they plan to change their process.

On February 19, 2002, ACMUI briefed the Commission and expressed a concern that if the draft final rule became effective 6 months after the publication date, there could be potential shortages of authorized individuals. Without changes in the draft final rule, the ACMUI was concerned that the boards would no longer be qualified for recognition by NRC. Thus, a board's future diplomats could no longer be granted authorized individual status by NRC or an Agreement State based on their board certification. The ACMUI argued that this might result in a shortage of authorized individuals.

Furthermore, the ACMUI expressed the concern that the boards may become "marginalized." Under the final rule, the pathway to gain authorized status through the board process would include all the requirements in the T&E process, which would require a specified length of training and a written certification signed by a preceptor. Because there are extra requirements for the board certification process, such as board written/oral examinations, potential candidates seeking authorized status may bypass the board certification pathway and select the simpler T&E process.

Based on these concerns, ACMUI urged the Commission to implement temporary measures to address the T&E issue in the draft final rule and to find a permanent solution after publication of the final rule. Subsequently, the staff changed the final rule by reinserting Subpart J (as contained in the proposed rule) for a 2-year transition period.

DISCUSSION:

There are three main reasons why the boards listed in Subpart J would no longer be qualified for recognition under the final rule.

1. T&E Requirements

Under the current Part 35, boards are not required to meet specific didactic/laboratory training and experience requirements to attain NRC recognition. Before a board was listed in Subpart J, ACMUI reviewed its certification program and determined the adequacy of the program. The T&E provisions of the final rule, however, specifically mandate that an individual must be certified by a medical specialty board whose certification process requires an individual to meet all the applicable requirements listed in Part 35 for the alternative pathway of the T&E process. This resulted in situations where the requirements of the board do not match the specific criteria of the final rule. A comparison between NRC's didactic/laboratory and experience requirements in the final rule and boards' requirements is presented in Attachment 1.

2. Preceptor Certification

Under the current rule, preceptor certification is not required for board certification. The final rule requires preceptor certification including a signature by an authorized individual. This requirement applies to both board certification and the T&E process. Attachment 1 provides a comparison between NRC's preceptor certification in the final rule and boards' certification or reference requirements. Some boards require certification by a qualified individual, such as the program director. However, this qualified individual need not necessarily be an authorized individual, as required of a preceptor by the final rule.

During the board certification process, the board makes its judgment that a candidate has satisfactorily completed the board's program and that the individual will be able to carry out the duties of this certification. The questions that could be raised are: (1) whether another qualified individual (e.g., a program director, a department head, or a professor) could also sign the certification; and (2) in the case of the board certification process, whether the members of the board could collectively act as a "preceptor."

3. New Modalities

The T&E requirements in the final rule were expanded to address two new modalities that were not considered in the current rule (i.e., remote after loader units and gamma stereotactic radiosurgery units, as described in 10 CFR 35.690). These requirements were geared to address unique health and safety issues raised by these modalities. However, the boards' programs do not specifically include T&E for the new modalities. This raises a concern as to how existing qualified individuals will obtain and demonstrate competence in radiation safety in a new modality.

The problem associated with the T&E requirements for new modalities can be illustrated as follows. If a medical institution has only a teletherapy unit and its AMP is authorized for teletherapy only, and the institution plans to add a High Dose Rate Remote After loader unit

(HDR), the questions that could be raised are: (1) what are the T&E requirements for the AMP to gain authorized status for HDR; (2) does the AMP need to go to another medical institution for additional training; (3) what is the length of training; (4) how many cases should the AMP perform independently; and (5) could the AMP receive the training for HDR in a manufacturer's facility or in a university setting, instead of another medical institution.

ACMUI AND OTHER STAKEHOLDERS' INPUT:

ACMUI formed a Subcommittee to develop recommendations on the T&E issue. A public Subcommittee meeting was held on June 21, 2002, at NRC. Representatives from more than 13 boards, associations, or societies participated in the meeting. In addition, more than 8 boards or societies provided written comments to ACMUI Subcommittee on its recommendations. After considering the comments from the meeting and letters, the Subcommittee developed a final recommendation and submitted it to the full committee for consideration. The staff noted that these interactions were substantive and that ACMUI appeared to be responsive to stakeholder concerns while still maintaining a clear focus on the desired radiation safety outcomes associated with adequate board certification criteria.

The ACMUI full Committee discussed the Subcommittee's recommendation via a public teleconference meeting on July 8, 2002. Members of the public and representatives from the Society of Nuclear Medicine participated in the conference call meeting. The ACMUI's report was submitted to NRC on August 1, 2002 (Attachment 2). The Subcommittee's recommendations and the ACMUI report were posted on the NRC website. Discussions at the public meetings primarily focused on the draft regulatory language contained in the Subcommittee recommendations.

ACMUI RECOMMENDATIONS:

The ACMUI indicates that the reasons why the boards recognized in Subpart J would no longer be qualified for recognition under the final rule are that the T&E provisions of the final rule: (1) require that a board's certification process include all of the T&E requirements in the alternative pathway; (2) require that the preceptor be an authorized individual who meets the requirements of the final rule, and (3) include new modalities not considered in the current rule.

The ACMUI states that, for completeness, its recommendations are written to resemble rule language. However, the ACMUI states that it is not the intention of the Committee to specify rule language.

As detailed in the ACMUI correspondence (Attachment 2), these recommendations are based on the following assumptions:

(1) Currently accepted boards should be listed explicitly in the regulations,

(2) To facilitate addition of future certification mechanisms to the T&E qualification process without rulemaking initiatives, criteria should be included in the rule to provide a basis for recognizing new boards,

(3) It is expected that the currently accepted boards will meet the criteria in (2),

(4) The preceptor concept should be modified to become documentation for completion of a training program rather than a testament to clinical competence, and

(5) Specific training should be required for certain new devices or modalities. This training is considered to be a separate requirement that is decoupled from the core training and supervised experience.

OPTIONS:

Option 1 No change in the final rule. Continue to require a board to meet the T&E requirements specified in the final rule, including didactic/laboratory training, work experience, and preceptor certification.

Option 2 Adoption of ACMUI recommendations. Prepare a proposed rule to modify the T&E requirements based on ACMUI recommendations and using the ACMUI suggested rule language as a starting point for the proposed rule and supporting regulatory analysis.

Option 3 Same as option 2 (i.e., adoption of ACMUI recommendations) except that all current or new boards that meet the criteria for recognition by NRC will be listed on the NRC website, not in the regulations.

COMPARISON OF OPTIONS:

Option 1, which affirms the requirements of the final rule, would require the boards to modify their certification programs as necessary to comply with the specified requirements. If the boards chose not to change, they could not continue to certify authorized individuals after the transition period ends. Candidates who desired to become authorized individuals would have to be certified through the T&E process. The burden for allowing authorized individuals to work would be increased because licensees would have to submit amendments and receive NRC approval before individuals certified through the T&E process could serve as authorized individuals. However, if boards chose not to modify their programs, the concerns for a potential shortage of authorized individuals would remain.

Under Option 2, the NRC would initiate rulemaking to propose modifying the regulations to specify separate T&E criteria for recognition of boards. The regulations would continue to specify T&E requirements for individuals seeking authorized status, specify separate T&E requirements for new modalities, and modify the preceptor certification to be signed by a qualified individual. Under this option, the concerns regarding the radiation safety for new modalities and the preceptor certification would be resolved. Option 2 is expected to increase stakeholder confidence because of the avoidance of concerns over potential disruption of medical services due to a shortage of authorized individuals. A disadvantage of this option is that, if some boards are listed in the rule and others on the NRC website, a licensee would not have a single location to verify qualified boards. In addition, if a board were to be deleted from the rule listing, the staff would have to amend the listing through rulemaking.

Option 3 is the same as Option 2 with the exception that all current and new boards that meet the criteria will be listed on the NRC website, not in regulations. Placing the currently approved boards and newly approved boards on the website would eliminate an unnecessary division between the two groups of boards. Individuals would not be required to review two locations for a listing of approved boards. Additional advantages include eliminating added burden on licensees and increasing the efficiency and effectiveness of NRC resources.

Adoption of the ACMUI recommendations would eliminate the problems for recognizing the boards without compromising radiation safety. In addition, listing all boards on the NRC website rather than listing some boards in the regulation and others on the website is more effective and efficient. The staff therefore recommends Option 3.

AGREEMENT STATES INPUT:

A draft of this Options Paper was forwarded to Agreement States for comment. Four comment letters were received: one each from States of Alabama, Illinois, Iowa, and Washington (Attachment 3).

Alabama recommended that the NRC adopt Option 1, with certain caveats. Iowa and Washington stated that the NRC appears to be proposing a lesser T&E standard for board-certified authorized users as compared to non-certified authorized users. They suggested that the certifying boards should be held to the same standards as the non-certified alternative (e.g., the certifying boards should be held to the same number of hours of T&E as specified in the final rule, such as 700 hours for imaging and localization studies). Although the requirements are not identical, the T&E standard for recognizing certifying boards would not be lesser than the standard for the non-certified alternative. The board certification process requires a candidate to have an academic degree, complete practical experience or a residency program, and pass an examination. The examination tests the knowledge and skills required to perform the activities responsible by the authorized users, including activities to ensure radiation safety. The staff considers that the combination of degree, practical experience, and examination in the criteria for recognizing certifying boards would be equivalent to the number of hours of didactic and experience specified for the non-certified alternative.

Washington stated that the preceptor requirement should be modified as recommended by ACMUI. However, Illinois suggested that NRC retain the preceptor certification in the final rule (i.e., including certification of competency) for individuals seeking to achieve authorized status through the alternative (i.e., non-board certification) pathway. For board certified individuals, Illinois expects that the board certification process contains prerequisites, inherent milestones, and internal certifications that are predictive of effective performance, and that therefore board certified individuals typically will be competent in the duties required by a medical use licensee. Alabama agreed that the NRC should allow the boards to accept another individual to sign on behalf of the actual preceptor, as long as the individual is the preceptor's supervisor, such as a department head or program director, and submits a list of the preceptors as reference. The staff will solicit ACMUI's input on whether the preceptor certification should be retained in the T&E requirements for the alternative pathway in preparing a proposed rule.

In addition, Illinois suggested adding a training requirement as paragraph (d)(1)(iv) in Section 35.12, "Application for license, amendment, or renewal," for emerging technologies (35.1000). The staff believes it is not necessary to add such a training requirement. This issue was considered during the development of the final rule. As explained in the Supplementary Information to the final rule, Section 35.1000 does not include any T&E requirements because there is no way of knowing what training requirements will be necessary for the safe use of byproduct material in new technologies. Applicants are required by 35.12(b) to provide information as to the T&E for the AU, ANP, or AMP as appropriate to the NRC, which will be evaluated on a case-by-case basis. See 67 FR 203321 (April 24, 2002).

Illinois further stated that the ACMUI should assume an active role in establishing specific training and experience criteria when future technologies are identified. After the criteria are established, the NRC should promptly post these criteria on the website. This would make them quickly available to the regulated community and the Agreement States. The staff is generally supportive of the recommendation, and it is consistent with our implementation plans for the new rule.

Both Illinois and Washington stated that they support ACMUI recommendations (except as stated above) and NRC's plan to list boards on the website, not in regulations.

AGREEMENT STATE COMPATIBILITY:

For Agreement States, adopting the new T&E requirements by October 24, 2005, would result in shortening the time frame to develop compatible T&E requirements. During the Organization of Agreement States (OAS) meeting in October 2002, the Agreement States voiced their concern regarding the adoption of compatible T&E requirements by October 24, 2005. The staff indicated at the meeting that it would provide States additional time after the OAS meeting, to submit any additional concerns regarding the timeline for adoption of the new rule. However, to date the staff has not received any additional comments. Therefore, the staff intends to proceed with a proposed rule and will specifically solicit comments from all stakeholders on the issue of the timing of the adoption of compatible T&E requirements by Agreement States.

COORDINATION:

The Office of the General Counsel has no legal objection to the use of any of the options presented in this paper. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

RESOURCES:

If the Commission adopts Option 3 associated with rulemaking, an initial estimate would be 0.5 FTE for the proposed rule and 0.4 FTE for the final rule. These resources are currently identified within the NMSS budget for rulemaking activities. No contractual support is anticipated.

SCHEDULE:

If the Commission accepts the staff recommendation, the staff endorses proceeding directly to develop a proposed rule without generating an additional rulemaking plan. Immediately developing a proposed rule will allow staff to meet the Commission’s directive in the SRM dated

April 16, 2002. The staff would work closely with the ACMUI and Agreement States for developing the proposed rule. In accordance with the Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs, the Agreement States have three years from the effective date of the Part 35 final rule to develop compatible requirements (i.e., no later than October 24, 2005).

It is expected that the proposed rule would be submitted to the Commission for approval approximately 6 months after Commission decision and direction through an SRM on a rulemaking, allowing time for Agreement State interaction. The final rule is expected to be submitted to the Commission for approval approximately 6 months after the closing of the public comment period for the proposed rule. This schedule will allow the revision to be effective before the end of the 2-year transaction period for Subpart J on October 24, 2004.

RECOMMENDATION:

That the Commission adopt Option 3 and direct the staff to proceed with a proposed rulemaking.

/RA/

William D. Travers
Executive Director
for Operations

Attachments:
1. Comparison Between NRC Requirements and Boards Certification Programs
2. ACMUI Recommendations
3. Agreement State Comment Letters

ATTACHMENT 1

COMPARISON BETWEEN NRC REQUIREMENTS AND BOARDS CERTIFICATION PROGRAMS

This Attachment contains tables showing comparisons between NRC's T&E requirements, as specified in the final rule, and the boards' certification programs.

The comparisons include the following authorized individuals:

Table 1	Radiation safety officer (§ 35.50)
Table 2	Authorized medical physicist (§ 35.51)
Table 3	Authorized nuclear pharmacist (§ 35.55)
Table 4	Authorized user in uptake, dilution, and excretion studies (§ 35.190)
Table 5	Authorized user in imaging and localization (§ 35.290)
Table 6	Authorized user in unsealed byproduct material requiring written directive (§ 35.390)
Table 7	Authorized user in manual brachytherapy sources (§ 35.490)
Table 8	Authorized user in remote after loader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.690)

Table 1 - Certification Requirements for Radiation Safety Officer (RSO) (35.50)

Final rule	Certification Through T&E Process			Certification Through Board Process
	(A) Didactic training	(B) Experience	(C) Certification	
	35.50(b)(1)(i) 200 hours in: 1. Rad phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Rad biology 5. Rad dosimetry	35.50(b)(1)(ii) One year supervised radiation safety experience in similar uses in: 1. Shipping/receiving & rad surveys 2. Performing checks on instruments 3.Securing/controlling byproduct material 4. Using controls to avoid mistakes in administration of byproduct material 5. Using procedures to prevent contamina & proper decontam 6. Using emergency procedures to control byproduct material 7.Disposing byproduct material	35.50(b)(2) Signed by a preceptor RSO that the individual satisfies (A) + (B) + can function independently	35.50 (a) (A) + (B) + (C) + Additional Board Requirements (e.g. examination)

Example of Boards Listed in Subpart J	Training/Education	Experience	Certification/ References	Additional Board Requirements
Am B of Health Physics In Comprehensive Health Physics	BS deg in physical science, engineering, or biological science with minor in physical science or eng.	6 yrs prof exp - at least 3 yrs in applied heath physics (MS, subst 1 yr exp; PhD subst 2 yrs)	**Certification**: Board Chairperson certifies met prof standards of the board **References**: The individual's supervisor; 2 other professionally qualified to evaluate candidates ability in HP(at least 1 certified)	Written Exam: Part I- fundamental HP; Part II- applied HP; covering 5 domains: measurements, regulation/standards, facilities/equipment, operation/procedure, education/training

Table 2 - Certification Requirements for Authorized Medical Physicist (AMP) (35.51)

Final rule	Certification Through T&E Process		Certification Through Board Process
	(A) Training & Experience	(B) Certification	
	35.51(b)(1) 1. Master/doctoral deg in physics, biophysics, radiological physics, or medical physics 2. One year training in therapeutic radiological physics 3. Additional year work experience under an AMP at medical institution, including the following specific tasks, as applicable: a. 35.67 Reqs for sealed sources & brachytherapy sources b. 35.433 Decay of Sr-90 sources c. 35.632 Full calibration measurements on teletherapy units d. 35.633 Full calibration meas on remote after loader units e. 35.635 Full calibration meas on gamma radiosurgery units f. 35.642 Periodic spot-check for teletherapy units g. 35.643 Periodic spot-check for remote after loader units h. 35.645 Periodic spot-check for gamma radiosurgery units i. 35.652 Radiation surveys	35.51(b)(2) Signed by a preceptor AMP who meets 35.51 that the individual satisfies (A) + can function independently for each type of therapeutic medical unit	35.51(a) (A) + (B) + Additional Board Requirements (e.g. examination)

Examples of Boards Listed in Subpart J:	Training/ Education	Experience	Certification/ References	Additional Board Requirements
A. Am B of Radiology in: 1.Therapeutic radiology physics 2. Roentgen ray and gamma ray physics 3. X-ray and Radium physics 4. Radiology physics	1.Bachelor deg in phy, eng, etc. and 2.Master/doc deg in med phy, phy, eng, etc. and 3.Formal course work in biological sciences	3 yrs exp with clinical department (MS subst 6 month, PhD subst 12 month) under supervision of cert physicist or radiologic physician	One certif physician & one certif physicist in the same specialty Physicist must directed the special training References must have personal knowledge of the applicant	**1. Written exam**: Part 1 includes measurements, radiation protection, clinical aspects of radiological physics Part 2 includes 3 subparts: Therapeutic phy; diagnostic phy, and medical nuclear phy (radioactive sources, calibration, rad protection). **2. Oral exam**: 5 parts, including radiation safety & patient safety, patient related measurement, equipment, etc.
B. Am B of Medical Physics in radiation oncology physics	Graduate deg in physics, med phy, or other related field	1. Clinical residency training from an accredited program or 2. MS-6 yrs, MS (med phy)-4 y MS(med phy, accredited)-3 y PhD-4 y PhD (med phy)-3 y PhD (m.p. accr)-2 y	2 Ltrs of endorsement to verify work experience and professional qualifications-must be from a certified medical physicist and a certified physician who practice in the medical specialty and who has personal Knowledge	**1. Written exam:** Part I: Fundamental medical physics, including radiation protection, radiation measurements Part II: For specialty areas in: medical health physics, radiation oncology phy, etc. **2. Oral exam:** include rad safety/hazards

Table 3 - Certification Requirements for Authorized Nuclear Pharmacist (ANP) (35.55)

Final rule	Certification Through T&E Process			Certification Through Board Process
	(A) 700 hrs structured educational program		(B) Certification	
	35.55(b)(1)(i) Didactic training in: 1. Rad phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Chemistry of byproduct material for med use 5. Rad biology	35.55(b)(1)(ii) Supervised practical experience in a nuclear pharmacy in: 1. Shipping/receiving & rad surveys 2. Performing checks on instruments 3. Calc, assay, & safely preparing dosages 4. Using controls to avoid mistakes in administration of byproduct material 5. Using procedures to prevent contamina & proper decontam	35.55(b)(2) Signed by a preceptor ANP that the individual satisf (A) + can function independently	35.55 (a) (A) + (B) + Additional Board Requirements (e.g. examination)

Example of Boards Listed in Subpart J	Training/ Education	Experience	Certification/ References	Additional Board Requirements
Board of Pharmaceutical Specialties as a nuclear pharmacist	1. Graduation from a pharmacy program accredited by Am Council on pharmaceutical Education 2. Must have current license to practice pharmacy	4000 hours experience (MS or PhD in nuclear pharmacy subst 2000hrs.)	None	Written exam in 9 domains, including health and safety domain

Table 4 - Certification Requirements for Authorized User in Uptake, Dilution, and Excretion Studies (35.190)

Final rule	Certification Through T&E Process			Certification Through Board Process
	(A) 60 hrs of Training and Experience		(B) Certification	
	35.190(c)(1)(i) Classroom and laboratory training in: 1. Radiation phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Chemistry of byproduct material for med use 5. Rad biology	35.190(c)(1)(ii) Work experience under AU (who meets 35.190, 290, or 390) in: 1. Ordering/receiving, unpacking, rad surveys 2. Calibrate dose instrument & performing checks on survey meter 3. Calc, measuring, & safely preparing dosages 4. Using controls to prevent medical events involving unsealed byproduct material 5. Using procedures to contain spills & proper decontam 6. Administering dosages	35.190(c)(2) Signed by a preceptor AU (who meets 35.190, 290, or 390) that the candidate satisfies (A) + can function independently	35.190(a) (A) + (B) + Additional Board Requirements (e.g. examination)

Example of Boards Listed in Subpart J	Training/ Education	Experience	Certification	Additional Board Requirements
Am B of Nuclear Medicine in nuclear medicine	1.Graduation from a medical school approved by the Liaison Committee on Medical Education 2. Valid license to practice of medicine	1. One or more yrs of preparatory post-doc training and 2. Two-yr formal residency training	Requires residency program directors to certify the applicant is competent in clinical nuclear medicine.	Written exam

Table 5 - Certification Requirements
Authorized User in Imaging and Localization Studies (35.290)

Final rule	Certification Through T&E Process			Certification Through Board Process
	(A) 700 hrs of Training and Experience		(B) Certification	
	35.290(c)(1)(i) Classroom and laboratory training in: 1. Radiation phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Chemistry of byproduct material for med use 5. Rad biology	35.290(c)(1)(ii) Supervised work under AU (who meets 35.290 or 35.390) in: 1. Ordering/receiving, unpacking, rad surveys 2. Calibrating dose instrument & performing checks on survey meter 3. Calc, measuring, & safely preparing dosages 4. Using controls to prevent medical events involving unsealed byproduct material 5. Using procedures to contain spills & proper decontam 6. Administering dosages 7. Eluting generator systems & preparing radioactive drugs	35.290(c)(2) Signed by a preceptor AU who meets 35.290 or 35.390 that the candidate satisfies (A) + can function independently	35.290(a) (A) + (B) + Additional Board Requirements (e.g. examination)

Example of Boards Listed in Subpart J	Training/ Education	Experience	Certification	Additional Board Requirements
Am B of Nuclear Medicine in nuclear medicine	1.Graduation from a medical school approved by the Liaison Committee on Medical Education 2. Valid license to practice of medicine	1. One or more yrs of preparatory post-doc training and 2. Two-yr formal residency training	Requires residency program directors to certify the applicant is competent in clinical nuclear medicine.	Written exam

Table 6 - Certification Requirements
Authorized User in Unsealed Byproduct Material Req Written Directive (35.390)

Final rule	Certification Through T&E Process			Certification Through Board Process
	(A) 700 hrs of Training and Experience		(B) Certification	
	35.390(b)(1)(i) Classroom and laboratory training in: 1. Radiation phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Chemistry of byproduct material for med use 5. Rad biology	35.390(b)(1)(ii) Supervised work under AU (who meets 35.290 or 35.390) in: 1. Ordering/receiving, unpacking, rad surveys 2. Calibrating dose instrument & performing checks on survey meter 3. Calc, measuring, & safely preparing dosages 4. Using controls to prevent medical events involving unsealed byproduct material 5. Using procedures to contain spills & proper decontam 6. Eluting generator systems & preparing radioactive drugs 7. Administering dosages (at least 3 cases in each of 4 categories)	35.390(b)(2) Signed by a preceptor AU who meets 35.390(a) or (b) and who has experience in same dose categories that the individual satisfies (A) + can function independently	35.390(a) (A) + (B) + Additional Board Requirements (e.g. examination)

Example of Boards Listed in Subpart J	Training/ Education	Experience	Certification	Additional Board Requirements
Am B of Nuclear Medicine	1.Graduation from a medical school approved by the Liaison Committee on Medical Education 2. Valid license to practice of medicine	1. One or more yrs of preparatory post-doc training and 2. Two-yr formal residency training	Requires residency program directors to certify the applicant is competent in clinical nuclear medicine.	Written exam

Table 7 - Certification Requirements for Authorized User in Manual Brachytherapy Sources (35.490)

Final rule	Certification Through T&E Process				Certification Through Board Process
	(A) Didactic	(B) Work Experience	(C) Clinical Experience	(D) Certification	
	35.490(b)(1)(i) 200 hours Classroom and laboratory training in: 1. Radiation phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Rad biology	35.490(b)(1)(ii) 500 hours work experience under AU (who meets 35.490) in: 1. Ordering/receiving, unpacking, rad surveys 2. Checking survey meters 3. Preparing, implanting, removing sources 4. Maintaining running inventories 5. Using controls to prevent medical events involving byproduct material 6 Using emergency procedures to control byproduct material	35.490(b)(2) 3 years supervised clinical experience under AU (who meets 35.490)	35.490(b)(3) Signed by a preceptor AU (who meets 35.490) that the individual satisfies (A) + (B) + (C) + can function independently	35.490(a) (A) + (B) + (C)+ (D) + Additional Board Requirements (e.g. examination)

Example of Boards Listed in Subpart J	Training/ Education	Experience	Certification	Additional Board Requirements
Am B of Radiology	1. Graduation from a medical school 2. Is a specialist in Radiation Oncology 3. Have high moral & ethical standards in his/her profession	five yrs - 4 yr must be in Radiation Oncology	A written statement from current program director of special training attesting that the applicant will have satisfactorily completed the required special training & will have achieved adequate professional qualifications for the exam in radiation oncology	1. Written exam 2. Oral exam

Table 8 - Certification Requirements for Authorized User in Remote Aterloader Units, etc. (35.690)

Final rule	Certification Through T&E Process				Certification Through Board Process
	(A) Didactic	(B) Work Experience	(C) Clinical Experience	(D) Certification	
	35.690(b)(1)(i) 200 hours Classroom and laboratory training in: 1. Radiation phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Rad biology	35.690(b)(1)(ii) 500 hours work experience under AU (who meets 35.690) in: 1. Reviewing full calibration & spot check 2. Preparing treatment plans & calc treatment dose/time 3. Using adm controls to prevent med events 4. Implementing emergency procedures for abnormal operation 5. Checking/using survey instruments 6 Selecting proper dose & how it is to be administered	35.690(b)(2) 3 years supervised clinical experience under AU (who meets 35.690)	35.690(b)(3) Signed by a preceptor AU (who meets 35.690 for each type relevant therapeutic unit) that the individual satisfies (A) + (B) + (C) + can function independently	35.490(a) (A) + (B) + (C)+ (D) + Additional Board Requirements (e.g. examination)

Example of Boards Listed in Subpart J	Training/ Education	Experience	Certification	Additional Board Requirements
Am B of Radiology	1. Graduation from a medical school 2. Is a specialist in Radiation Oncology 3. Have high moral & ethical standards in his/her profession	five yrs - 4 yr must be in Radiation Oncology	A written statement from current program director of special training attesting that the applicant will have satisfactorily completed the required special training & will have achieved adequate professional qualifications for the exam in radiation oncology.	1. Written exam 2. Oral exam

ATTACHMENT 2

ACMUI RECOMMENDATIONS

August 1, 2002

RECOMMENDATIONS OF THE NRC ACMUI SUBCOMMITTEE ON TRAINING AND EXPERIENCE REQUIREMENTS

INTRODUCTION

A revision of 10 CFR Part 35, Medical Use of Byproduct Material, was published on April 24, 2002 (Federal Register Vol. 67(79) 20371-20397). The revision contains new training and experience requirements for individuals to become authorized as a radiation safety officer (RSO), authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), and authorized user (AU). These new requirements provide several options for individuals to become authorized. One option is for individuals to be certified by a specialty board whose certification process includes all the requirements in an alternate pathway. The alternate pathway includes specified numbers of hours of training and written certification signed by a preceptor that the individual has satisfactorily completed the training requirements and has achieved a level of competency sufficient to function independently as an RSO, AMP, ANP, or AU. Currently, most specialty boards do not require candidates to meet these specific requirements.

The Advisory Committee on Medical Uses of Isotopes (ACMUI) appointed a subcommittee on training and experience requirements to develop recommendations that would restore board certification as the default pathway for individuals to become authorized as RSO, AMP, or AU. The subcommittee held a meeting on June 21 in Rockville, Maryland and a meeting on July 8 by conference call to discuss draft recommendations and to receive public input. The following recommendations include consideration of discussion from these meetings.

For completeness these recommendations are written to resemble rule language. However, it is not the intention of the subcommittee to specify rule language.

RATIONALE

These recommendations are based on the following assumptions:

(1) Currently accepted boards should be listed explicitly in the regulations;
(2) To facilitate addition of future certification mechanisms to the T&E qualification process without rulemaking initiatives, criteria should be included in the rule to provide a basis for recognizing new boards;
(3) It is expected that the currently accepted boards will meet the criteria in (2);
(4) The preceptor concept should be modified to become documentation for completion of a training program rather than a testament to clinical competence; and;
(5) Specific training should be required for certain new devices or modalities. This training is considered to be a separate requirement that is decoupled from the core training and supervised experience.

The intent of these recommendations is to provide minimum training and experience requirements for an individual to become an AMP, ANP, AU, or RSO. The objective of these requirements is to assure the safe use of byproduct material used in medical practice.

Several pathways are provided to demonstrate adequate knowledge of the safe use of byproduct material. For AMP, ANP, RSO, and most categories of use for AU, adequate knowledge may be demonstrated by obtaining certification by a specialty board. The subcommittee's examination of various specialty board criteria for admission of candidates revealed that few specialty boards meet the specific requirements of revised Part 35 published April 24, 2002. However, the subcommittee concluded that individuals who had completed the certification process by appropriate specialty boards had demonstrated adequate knowledge in the safe use of byproduct material for their specialty. Thus the subcommittee recommends that these boards be specifically listed as approved boards.

Additional specialty boards may be identified in the future. Therefore, the subcommittee developed specific criteria for recognition of specialty boards. To the best of our knowledge, those specialty boards that are listed in these recommendations meet these specific criteria.

As an alternative to board certification, an individual may demonstrate completion of specified training and experience requirements as provided in revised Part 35.

In addition to meeting the minimum training and experience requirements, authorized individuals would be expected to demonstrate training or experience in the use of byproduct material or specific modalities, as appropriate, which are identified on the licensee's license. This would require a licensee to assure that newly hired authorized individuals have appropriate training and experience and that current authorized individuals receive appropriate training when a new modality is added to the licensee's program.

§ 35.50 Training for Radiation Safety Officer

Except as provided in § 35.57, the licensee shall require the an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who –

(a) Is certified by:
  (1) American Board of Health Physics in Comprehensive Health Physics;
  (2) American Board of Medical Physics in Medical Health Physics; or
  (3) American Board of Science in Nuclear Medicine in Radiation Protection; or

(b) Is certified by a specialty board whose certification has been recognized by the Commission and requires all diplomats:
  (1) To hold a bachelors 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;
  (2) To have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics;
  (3) To provide a written statement from the supervising physicist or Radiation Safety Officer attesting that the individual has completed the training and experience described in paragraph (b)(2) of this section; and
  (4) To pass an examination administered by diplomats of the specialty board, which evaluate knowledge and competence in radiation physics and

instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, and radiation biology; or

(c) (1) Has completed a structured educational program consisting of 200 hours of didactic training in the following areas--
- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Radiation biology; and

(2) Has one year of full-time radiation safety experience under the supervision of an individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes similar types(s) of use(s) of byproduct material involving the following--
- (i) Shipping, receiving, and performing related radiation surveys;
- (ii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
- (iii) Securing and controlling byproduct material;
- (iv) Using administrative controls to avoid mistakes in the administration of byproduct materials;
- (v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
- (vi) Using emergency procedures to control byproduct material; and
- (vii) Disposing of byproduct material; and

(3) Has provided a written statement from the supervising physicist(s) or Radiation Safety Officer(s) attesting that the individual has completed the training and experience described in paragraph (c)(1) and (c)(2) of this section; or

(d) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities.

(e) In addition to meeting the requirements of (a), (b), (c), or (d) of this section, the licensee shall require a Radiation Safety Officer to have training in the radiation safety, regulatory issues, emergency procedures, and proposed clinical procedures of any modality for which the licensee seeks authorization. This training requirement may be satisfied by completing training that is supervised by an Authorized Medical Physicist, Authorized User, or Radiation Safety Officer as appropriate, who is authorized for the modality for which the licensee is seeking authorization.

§ 35.51 Training for an Authorized Medical Physicist.

Except as provided in § 35.57, the licensee shall require the authorized medical physicist to be an individual who –

(a) Is certified by the one of the following specialty boards in radiation oncology physics (“radiation oncology physics” understood to be that branch of medical or radiological physics that is applied to clinical practice of radiation oncology)
- (1) American Board of Radiology in therapeutic radiological physics;
- (2) American Board of Radiology in roentgen ray and gamma ray physics;

(3) American Board of Radiology in x-ray and radium physics;
(4) American Board of Radiology in radiological physics; or
(5) American Board of Medical Physics in radiation oncology physics; or

(b) Is certified by a specialty board in radiation oncology physics whose certification has been recognized by the Commission and requires all diplomats;
(1) To hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an institution accredited by a regional accrediting body;
(2) To have two years of full-time practical training and/or supervised experience in radiation oncology physics
(i) Under the supervision of a medical physicist who is certified in radiation oncology physics by the board in question, a board specified in paragraph (a) of this section; or a specialty board recognized by the Commission according to this paragraph (b) of this section
(ii) In a clinical radiation oncology facility providing megavoltage external beam therapy and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 35.400 or 35.600;
(3) To obtain a written statement from a medical physicist, certified by a specialty board listed in paragraph (a) of this section or recognized by the Commission according to paragraph (b) of this section and who has personal knowledge of the candidate’s training and experience, attesting that the individual has satisfactorily completed the training and experience described in paragraph (b)(2) of this section; and
(4) To pass an examination administered by diplomats of the specialty board, which assesses knowledge and competence in clinical radiation oncology, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy and stereotactic radiosurgery; or

(c) (1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an institution accredited by a regional accrediting body;
(2) Has completed 1 year of full-time training in radiation oncology physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the modality in which the individual is seeking authorization in a clinical radiation oncology facility that provides megavoltage external beam therapy and brachytherapy services that include
(i) performing sealed source leak tests and inventories;
(ii) performing decay corrections;
(iii) performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
(iv) conducting radiation surveys around external beam, remote afterloading and stereotactic radiosurgery units as applicable; and
(3) Has obtained a written statement from the supervising medical physicist attesting that the individual has satisfactorily completed the training and experience described in paragraph (c)(2) of this section and identifies the byproduct material modalities included.

(d) In addition to meeting the requirements of (a), (b), or (c) of this section, an authorized medical physicist must have training in the modality for which authorization is sought that includes “hands on” device operation, safety procedures, clinical use, and operation of treatment planning system. This training requirement may be satisfied by satisfactorily completing a training program provided by the vendor or by training supervised by an AMP authorized for the modality in which the individual is seeking authorization.

§ 35.55 Training for an authorized nuclear pharmacist.

Except as provided in § 35.57, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who --

(a) Is certified as a nuclear pharmacist by Board of Pharmaceutical Specialties in Nuclear Pharmacy; or

(b) Is certified as a Nuclear Pharmacist by a Nuclear Pharmacy specialty board whose certification process has been recognized by the Commission and requires that all diplomats:

(1) Have graduated from a pharmacy program accredited by the American Council On Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience.

(4) Pass an examination in nuclear pharmacy administered by diplomats of the specialty board, which assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(c) (1) Has completed 700 hours in a structured educational program applicable to consisting of

(i) Didactic 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) Supervised practical experience in a nuclear pharmacy involving --

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid medical events in the administration of byproduct material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained a written statement signed by a preceptor authorized nuclear pharmacist (ANP) attesting that the individual has completed the required training listed in (c)(1)(ii) of this section.

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

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

(a) Is certified in--

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;

(5) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

(b) Is certified by a medical specialty board whose certification has been recognized by the Commission and:

(1) Includes all of the requirements in paragraph (d) of this section; and

(2) Requires diplomats to pass an examination administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(c) Is an authorized user under Secs. 35.290 or 35.390 or equivalent Agreement State requirements; or

(d) (1) Has completed 60 hours of training and experience in basic radionuclide handling techniques 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, under the supervision of an authorized user who meets the requirements in Sec. 35.190, Sec. 35.290, or Sec. 35.390 or equivalent Agreement State requirements, involving--

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained a written statement, signed by a preceptor authorized user who meets the requirements in Secs. 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, or, if the training was received in conjunction with a residency or fellowship program, a written statement signed by the training program director, attesting that the individual has satisfactorily completed the requirements in paragraph (d)(1) of this section.

Sec. 35.290 Training for imaging and localization studies.

Except as provided in Sec. 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under Sec. 35.200 to be a physician who--

(a) Is certified in--

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;

(5) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine;

(6) Nuclear cardiology by the Certification Board of Nuclear Cardiology; or

(b) Is certified by a medical specialty board whose certification process has been recognized by the Commission and:

(1) Includes all of the requirements in paragraph (d) of this section; and

(2) Requires diplomats to pass an examination administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(c) Is an authorized user under Sec. 35.390 or equivalent Agreement State requirements; or

(d) (1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum,--

(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;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in Secs. 35.290 or 35.390 or equivalent Agreement State requirements, involving–

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;
(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
(F) Administering dosages of radioactive drugs to patients or human research subjects; and
(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained a written statement, signed by a preceptor authorized user who meets the requirements in Secs. 35.290 or 35.390 or equivalent Agreement State requirements, or, if the training was received in conjunction with a residency or fellowship program, a written statement signed by the training program director, attesting that the individual has satisfactorily completed the requirements in paragraph (d)(1) of this section.

Sec. 35.390 Training for use of unsealed byproduct material for which a written directive is required.

Except as provided in Sec. 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under Sec. 35.300 to be a physician who

(a) is certified by
(1) The American Board of Nuclear Medicine;
(2) The American Board of Radiology in radiation oncology;
(3) The Royal College of Physicians and Surgeons of Canada in nuclear medicine or radiation oncology;
(4) The British Royal College of Radiology in radiation oncology; or
(5) The American Osteopathic Board of Radiology in radiation oncology; or

(b) Is certified by a medical specialty board whose certification has been recognized by the Commission and requires all diplomats
(1) To successfully complete a minimum of three years of residency training in a radiation oncology or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in paragraphs (c)(1) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;
(2) To provide a written statement from the residency program director attesting to successful completion of the training requirement in paragraph (b)(1) of this section and;
(3) To pass an examination administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material; or

(c) (1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. This 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, under the supervision of an authorized user who meets the requirements in Sec. 35.390(a), Sec. 35.390(b), or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in Sec. 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., Sec. 35.390(b)(1)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status. This work experience must involve--

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determined the activity of dosages, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(F) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written statement attesting that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section. The written statement must be signed by a preceptor authorized user who meets the requirements in Sec. 35.390(a), Sec. 35.390(b), or equivalent Agreement State requirements, or, if the training was received in conjunction with a residency or fellowship program, the written statement must be signed by the training program director. The preceptor authorized user, who meets the requirements in Sec. 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., Sec. 35.390(d)(1), (2), (3), or (4)) as the individual requesting authorized user status.

(d) In addition to meeting the requirements of (a), (b), or (c) of this section, an authorized user of byproduct material authorized under 35.300 must have experience, under the supervision of an authorized user, administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status—

(1) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) or sodium iodide I-131;
(2) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) or sodium iodide I-131. Experience with at least three cases in Category (d)(2) also satisfies the requirement in Category (d)(1);
(3) Parenteral administration of therapeutic quantities of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV;
(4) Parenteral administration of any other radionuclide in therapeutic quantities.

Sec. 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).

(c) (3) Has obtained written statement attesting that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section. [**competency statement removed].** The written certification must be signed by **[….remainder of paragraph unchanged]**

Sec. 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).

(c) (3) Has obtained written statement attesting that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section. [**competency statement removed].** The written certification must be signed by **[….remainder of paragraph unchanged]**

Sec. 35.490 Training for use of manual brachytherapy sources.

Except as provided in Sec. 35.57, the licensee shall require an authorized user of a manual brachytherapy for the uses authorized under Sec. 35.400 to be a physician who—

(a) Is certified by
  (1) The American Board of Radiology in radiation oncology;
  (2) The Royal College of Physicians and Surgeons of Canada in radiation oncology;
  (3) The British Royal College of Radiology in radiation oncology; or
  (4) The American Osteopathic Board of Radiology in radiation oncology; or
(b) Is certified by a medical specialty board whose certification has been recognized by the Commission and requires all diplomats
  (1) To successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;
  (2) To obtain a written statement from the residency program director attesting to successful completion of the training requirement in paragraph (b)(1) of this section and;
  (3) To pass an examination administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of high and low dose-rate brachytherapy; or

(c) (1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of manual brachytherapy sources that includes--

(i) 200 hours of 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; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Sec. 35.490 or equivalent Agreement State requirements at a medical institution, involving--

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys:

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(D) Maintaining inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material;

(F) Using emergency procedures to control byproduct material; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Sec. 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (c)(1) of this section; and

(3) Has obtained a written statement attesting that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section. The written certification must be signed by the supervising authorized user or if the training was obtained in a residency training program, by the program director.

Sec. 35.491 Training for ophthalmic use of strontium-90.

(b) (3) Has obtained a written statement signed by a preceptor authorized user who meets the requirements in Sec. 35.490, Sec. 35.491, or equivalent Agreement State requirements, attesting that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section. **[competency statement removed].**

Sec. 35.590 Training for use of sealed sources for diagnosis.

Except as provided in Sec. 35.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under Sec. 35.500 to be a physician, dentist, or podiatrist who–

(a) Is certified in–
  (1) Diagnostic radiology, or radiation oncology by the American Board of Radiology;
  (2) Nuclear medicine by the American Board of Nuclear Medicine;
  (3) Diagnostic radiology by the American Osteopathic Board of Radiology; or
  (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(b) Is certified by a specialty board whose certification has been recognized by the Commission and includes all of the requirements in paragraph (c) of this section; or

(c) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include--
  (1) Radiation physics and instrumentation;
  (2) Radiation protection;
  (3) Mathematics pertaining to the use and measurement of radioactivity; and
  (4) Radiation biology.

(d) In addition to meeting the requirements of paragraph (a), (b), or (c) of this section, an authorized user under this section must have training in the use of the device for the uses requested.

Sec. 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Except as provided in Sec. 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under Sec. 35.600 to be a physician who—

(a) Is certified by
  (1) The American Board of Radiology in radiation oncology;
  (2) The Royal College of Physicians and Surgeons of Canada in radiation oncology;
  (3) The British Royal College of Radiology in radiation oncology; or
  (4) The American Osteopathic Board of Radiology in radiation oncology; or

(b) Is certified by a specialty board whose certification has been recognized by the Commission and requires all diplomats
  (1) To successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;
  (2) To obtain a written statement from the residency program director attesting to successful completion of the training requirement in paragraph (b)(1) of this section and;
  (3) To pass an examination administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, high and low dose-rate brachytherapy, and external beam therapy; or

(c) (1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes--

(i) 200 hours of 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; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Sec. 35.690 or equivalent Agreement State requirements at a medical institution, involving--

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Sec. 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (c)(1) of this section; and

(3) Has obtained a written statement attesting that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this. The written statement must be signed by the supervising authorized user or if the training was obtained in a residency training program, by the program director.

(d) In addition to meeting the requirements of paragraphs (a), (b), or (c) of this section, an authorized user of a sealed source authorized under 35.600 must have training in the modality for which authorization is sought. This includes training in device operation, safety procedures, and clinical use. This training requirement may be satisfied by satisfactorily completing the training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the modality in which the individual is seeking authorization.

ATTACHMENT 3

AGREEMENT STATES COMMENT LETTERS

From: "Johns, George" <GJOHNS@health.state.ia.us>
To: "'lmp1@nrc.gov'" <lmp1@nrc.gov>
Date: 8/8/02 12:29PM
Subject: Iowa's response to Draft Options Paper on Part 35 Training and Experience

The Chief of Iowa's Bureau of Radiological Health has reviewed the following and requested that it be forwarded to you.

The current rule requires 200 hours of classroom training, 500 hours of supervised clinical experience and 500 hours of supervised work experience for use of radiopharmaceuticals in imaging and localization studies. The new rule states that a physician must only have 750 hours and is non-specific. Based on the Draft Options Paper, it would appear that the board certifications do not even meet the reduced standards, which take effect October 24, 2002. In other words, despite a 500-hour reduction in the training and experience requirements, only the Certification Board of Nuclear Cardiology meets the new NRC standards.

If the board certification process includes testing, which effectively evaluates a physician's didactic and clinical knowledge, IDPH would normally have little problem accepting that certification. However, because the regulatory community is tasked with promulgating rules to protect the health and safety of the patient, the staff, and the physician, the question that arises is: How much training can be avoided without compromising health and safety?

It seems odd that a certifying body would not be interested in establishing consistent training and experience standards. IDPH does not agree that the standards should be altered to accommodate the boards.

The certification process, if properly designed, can be used to determine competency. However, when considering training for non-board certified physicians, the difficulty that arises is determining how much training and experience should be required in lieu of a board certification. I believe that the primary objection expressed by many other Agreement States is that the NRC appears to be proposing a lesser training and experience standard for physicians with a board certification. Again, the standard has already been diminished. At what point does the NRC wish to say that the level of training is too little? It would appear that the NRC believes that the certification boards are capable of making that decision. It is Iowa's opinion that the NRC should not abdicate its responsibility.

In summary, the NRC has determined that regulations pertaining to training

and experience are a Compatibility B. The final rule has already reduced the training and experience requirements to a level that many believe to be compromising health and safety. The standard should not be further compromised. Therefore, the certifying boards, which have inconsistent standards among themselves, should be held to the new standards. Board certified and non-certified physicians should meet those same standards. Finally, if Agreement States are required to be consistent with the NRC, IDPH believes that the training and experience for physicians should be also consistent.

From: "Frazee, Terry" <Terry.Frazee@DOH.WA.GOV>
To: "'LMP1@nrc.gov'" <LMP1@nrc.gov>
Date: 8/27/02 1:28PM
Subject: STP-02-061 -- Comments on Part 35 T&E

I have reviewed the Draft Options Paper presented on the Technical Conference Forum and have the following comments:

The ACMUI request is proof of what the Agreement States have known for a long time -- "Authorized Users" are clinicians (or "authorized prescribers", if you will) and, for the most part, NOT "users" or "handlers" of radioactive material; and obviously the Board process reflects that. The new T&E regulations (Option 1) are written as minimum requirements for the "use" or handling of radioactive material, i.e., with radiation safety in mind, and should be maintained "as is". An eleventh hour realization that the "clinical practice" Boards are "just that" does not negate the value of the T&E requirements geared to radiation safety!

Bottom line: The training and experience requirements represent the MINIMUM radiation safety requirements applicable to ALL "users" (even Board certified individuals) and should be kept for ALL. We don't "buy" the shortage argument. The Boards have two years to show how they meet (or will meet) or exceed the minimum requirements. Even if the ACMUI (rather than NRC staff) is used to "approve" Boards, the standard should be the same. Professional judgment can be used, BUT the STANDARD remains the same. The concern that "candidates seeking authorized user status may bypass the board certification pathway and select the simpler T&E process" is more reflective of Board concern for losing its candidates than for diminution of radiation safety. Our concern as regulators should be that the individuals we approve as "authorized users" are adequately trained with sufficient experience to handle the radioactive materials safely. Our first responsibility is to "do it right", not just pick the "easy way".

Therefore:

1. Leave the basic T&E alone. A lot of time and effort has been expended getting the "minimum" radiation safety standard to this point. "Last minute" changes are suspect.

2. Modify the certification (preceptor) requirement as recommended by ACMUI. This makes sense for Board certifications and further makes it clear that radiation safety rather than clinical skills are the focus of the regulatory requirement.

3. Set specific training requirements for new devices or modalities that can build upon the basic requirements for existing modalities. Existing authorized users should already have the basic radiation safety training and

experience and need only specific training for the new device or modality.

4. Publish "Approved Boards" on the web site (and not in regulation) for ease and convenience of all concerned.

If there are any lessons to be learned here, one is: "license the techs" and leave the physicians to their Boards (with ACMUI setting the bar for "authorized prescribers"); and the other is: last minute jockeying to change the "standard" means the rule may not be "perfect" and therefore "casting it in concrete" (compatibility B) may be premature!

Note to Agreement States: comments are due by August 30!

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"The Department of Health works to protect and improve the health of people in Washington State"
****
This message from Terry C. Frazee
e-mail terry.frazee@doh.wa.gov

Quick ways to reach me:
Voice = 360-236-3221
FAX = 360-236-2255

Also, visit our Home Page at
http://www.doh.wa.gov/ehp/rp

CC: "NRC-Lloyd (E-mail)" <lab@nrc.gov>, "AL-KirkseyWhatley (E-mail)" <kwhatley@adph.state.al.us>, "AR-JaredThompson (E-mail)" <jwthompson@healthyarkansas.com>, "AZ-AubreyGodwin (E-mail)" <agodwin@arra.state.az.us>, "CA-EdBailey (E-mail)" <EBailey@dhs.ca.gov>, "CA-KentPrendergast (E-mail)" <KPrender@dhs.ca.gov>, "CO-JakeJacobi (E-mail)" <jake.jacobi@state.co.us>, "FL-BillPassetti (E-mail)" <bill_passetti@doh.state.fl.us>, "GA-TomHill (E-mail)" <thill@dnr-gwia2.dnr.state.ga.us>, "IA-Flater (E-mail)" <dflater@idph.state.ia.us>, "IL-Collins (E-mail)" <collins@idns.state.il.us>, "KS-TomConley (E-mail)" <tconley@kdhe.state.ks.us>, "LA-MikeHenry (E-mail)" <m_henry@ldeq.org>, "MD-RolandFletcher (E-mail)" <rfletcher@mde.state.md.us>, "MA-Hallisey (E-mail)" <bob.hallisey@state.ma.us>, "MS-RobertGoff (E-mail)" <rgoff@msdh.state.ms.us>, "NC-BevHall (E-mail)" <beverly.hall@ncmail.net>, "ND-KenWangler (E-mail)" <kwangler@state.nd.us>, "ND-TerryOclair (E-mail)" <toclair@state.nd.us>, "NE-JuliaSchmitt (E-mail)" <julia.schmitt@hhss.state.ne.us>, "NH-WayneJohnston (E-mail)" <wjohnsto@dhhs.state.nh.us>, "NM-BillFloyd (E-mail)" <william_floyd@nmenv.state.nm.us>, "NV-StanMarshall (E-mail)" <smarshall@bhps.state.nv.us>, "NYCH-GeneMiskin (E-mail)" <gmiskin@health.nyc.gov>, "NYDEC-Merges (E-mail 2)" <pjmerges@gw.dec.state.ny.us>, "NYDOL-Brandt (E-mail)" <usccjb@labor.state.ny.us>, "NYSH-Salame-Aflie (E-mail)" <asa01@health.state.ny.us>, "OH-Suppes (E-mail)" <rsuppes@gw.odh.state.oh.us>,

"OK-MikeBroderick (E-mail)" <mike.broderick@deq.state.ok.us>, "OR-TerryLindsey (E-mail)" <terry.d.lindsey@state.or.us>, "RI-MarieStoeckel (E-mail)" <maries@doh.state.ri.us>, "SC-HenryPorter (E-mail)" <porterhj@dhec.state.sc.us>, "SC-PearceO'Kelley (E-mail)" <okelletp@dhec.state.sc.us>, "TN-EddieNanney (E-mail)" <enanney@mail.state.tn.us>, "TX-McBurney (E-mail)" <ruth.mcburney@tdh.state.tx.us>, "TX-Ratliff (E-mail)" <richard.ratliff@tdh.state.tx.us>, "UT-Sinclair (E-mail)" <bsinclair@utah.gov>, "Demaris, Curt" <Curt.Demaris@DOH.WA.GOV>, "Robertson, Gary" <Gary.Robertson@DOH.WA.GOV>

STATE OF ILLINOIS
DEPARTMENT OF NUCLEAR SAFETY
1035 OUTER PARK DRIVE • SPRINGFIELD, ILLINOIS 62704
217-785-9900 • 217-782-6133 (TDD)

George H. Ryan
Governor

Thomas W. Ortciger
Director

September 11, 2002

U.S. Nuclear Regulatory Commission
ATTN: Linda M. Psyk, NMSS
Mail Stop TWFN 8-F-5
Washington, D.C. 20555

Re: Draft Options Paper, Part 35 - Training and Experience Requirements (STP-02-061)

Dear Ms. Psyk:

The Illinois Department of Nuclear Safety hereby submits the following comments on the above-identified draft options paper. The paper describes a recommendation by the NRC's Advisory Committee for Medical Use of Isotopes (ACMUI). The recommendation suggests a basis for the NRC to recognize training approved by professional specialty boards and provides an alternative training and experience pathway for individuals without board certification. It also proposes training and experience requirements for those working with remote afterloaders and gamma stereotactic radiosurgery units. The options paper concludes that the NRC should accept the advisory committee's recommendation.

Except for misgivings about the ACMUI's idea for the preceptor concept, the Department of Nuclear Safety does not object to either the advisory committee's recommendation or the NRC's plan to list recognized specialty boards on its website instead of in Part 35. We believe that with one additional change, the ACMUI's recommendation would provide effective training and experience requirements. We also have suggestions that would clarify the NRC's expectations for training of individuals working with future technologies.

The Preceptor Concept. We strongly oppose the idea of reducing the amount of assurance required of a preceptor when vouching for an individual seeking authorized status on a medical use license. The revision of Part 35 that will go into effect on October 24, 2002, requires a preceptor to verify that the individual is competent to

perform independently the duties required by a medical use license. The Department of Nuclear Safety believes that this principle must be preserved if the revision is to be effective over time.

The ACMUI recommends two traming and experience pathways leading to authorized status on a license. The more common track is certification by a professional specialty board. The Department of Nuclear Safety supports the ACMUI's vision of how this should be done. We believe that the board certification process contains prerequisites, inherent milestones, and internal certifications that are predictive of effective performance by board-certified individuals. We expect these individuals typically to be competent in the duties required by a medical use license.

The alternative training and experience pathway provides a method other than board certification for an individual to achieve authorized status on a medical use license. It allows the individual to acquire training and experience and then furnish a preceptor statement asserting that he or she is prepared to effectively perform the duties required by a license. Although this is a valid process overall, we strongly oppose the ACMUI's idea of reducing the assurance that would be required of a preceptor. Instead of an attestation of competency, the ACMUI wants the NRC to require only verification that training was completed. Thus, the NRC is asked to accept less assurance of competency from the alternative pathway than through board certification.

The NRC removed many prescriptive requirements from the revision of Part 35, in part because of assurances that the regulated community would assume increased responsibility for the performance of its members. Indeed, when the revision was being drafted, the ACMUI was not opposed to preceptors appraising the competence of individuals seeking authorized status on medical use licenses. We believe that the ACMUI recognized the need for increased self-regulation if Part 35 were to become more performance-based.

In the interim, however, it appears that a misunderstanding has arisen between the ACMUI and the NRC. We believe that the wording of the revision of Part 35 has led the ACMUI to conclude that the NRC is seeking a guarantee of clinical competency. Instead of such a broad guarantee, we believe that the NRC actually requires only an *opinion* about the ability of an individual to independently perform the *duties required by a license.* This opinion would not require the preceptor to vouch for the individual's overall clinical competency.

We believe that the positions of both the NRC and the regulated community would be served if this nuance were clarified. Here is a suggestion to modify the several requirements for preceptor statements in Part 35:

> Has obtained a written statement attesting that the individual has satisfactorily completed the requirements in paragraph_____ of this section. The written statement shall be signed by a preceptor_____ who meets the requirements in _____ or equivalent Agreement State requirements, and shall include verification that, to the preceptor's best knowledge, the individual is competent to function independently as an_____ for-the medical uses authorized under_____ .

Future Technologies. The ACMUI's recommendation includes a training requirement for remote afterloaders and gamma stereotactic radiosurgery units. The recommendation would require modality-specific training in device operation, safety procedures, and clinical use. The Department of Nuclear Safety supports this recommendation.

Besides the training requirements for the above modalities, however, we suggest that the NRC also identify its training expectations for future technologies. Here is a clarification to subsection 35.12(d) of Part 35 that we believe would accomplish this:

> 35.12(d)(1)(iv) Specialized training beyond that described in paragraph (b)(l) of this section. A radiation safety officer, authorized user, authorized medical physicist, or authorized nuclear pharmacist for a use authorized under section 35.1000 shall have training in the use for which authorization is sought. This includes training in device operation, safety procedures, and clinical use. This training requirement may be satisfied by satisfactorily completing the training program provided by the vendor for the appropriate position. It may also be satisfied by receiving training supervised by a radiation safety officer, authorized user, authorized medical physicist, or authorized nuclear pharmacist, as appropriate, who is authorized for the use for which authorization is sought.

A Role for the ACMUI. The Department of Nuclear Safety believes that the ACMUI should assume an active role in establishing specific training and experience criteria for future technologies. We suggest that the NRC ask the advisory committee to recommend training specifics for each new use under section 35.1000. This recommendation should describe the training and experience qualifications necessary under paragraph (b)(l) of section 35.12. It should also specify the number of hours or cases required to satisfy the specialized training requirement suggested above [new paragraph (d)(1)(iv)]. This practice would capitalize on the advisory committee's familiarity and expertise in new technologies.

After evaluating the ACMUI's recommendation, the NRC should promptly post new training and experience requirements on its website. This would make them quickly available to the regulated community and the Agreement States, thereby standardizing requirements for new technologies as they emerge.

Thank you for the opportunity to comment on this draft options paper. My telephone number is 217-785-9930 if you have questions or comments.

Sincerely,

Joseph G. Klinger, Chief
Division of Radioactive Materials

JGK:kjg

cc: Jim Lynch
NRC Region III

Linda M. Psyk, NMSS
U.S. Nuclear Regulatory Commission
Mail Stop TWFN 8-F-5
Washington, DC 20555

Re: STP-02-061 - Part 35 - Training and Experience Requirements

Dear Ms Psyk:

This letter serves as my comment on the above referenced document. I have submitted comments to you earlier, via e-mail, regarding the ACMUI Subcommittee recommendation dated July 17, 2002.

In reading the above document, I find some inaccurate statements. The following is my response to each of these items.

1) If the draft final rule became effective 6 months after the publication date, there could be potential shortages of authorized individuals.

Response: This appears to be a key item of concern to the ACMUI. However, I fail to see the problem. During the last few years, nuclear cardiologists have not had a board certification available to them, yet there has been no shortage of nuclear cardiologists applying for, and receiving, authorized user status.

2) The ACMUI expressed concern that the boards may become "marginalized", because potential candidates seeking authorized user status may bypass the board certification pathway and select the simpler T&E process.

Response: When the NRC revised Part 35 in the 1980's, the various boards were queried as to their radiation safety requirements for board eligibility. These requirements became the basis for the optional training and experience requirements. Therefore, an individual who was not board certified, was required to be board eligible (in regards to radiation safety) in order to be approved as an authorized user. If any changes were made to the radiation safety training and experience required to sit for a board listed in Part 35, the NRC should have been made aware so they could review the possible impacts on radiation safety.

During the rule revision process, the Part 35 Working Group (of which I was a member) spent many hours with the ACMUI as well as their subcommittees for diagnostic and therapeutic uses. Many changes were made in the training and experience requirements

based on the discussions and recommendations of the members. It was made very clear that only those boards that showed they required that a board candidate meet the optional training and experience requirements would be "recognized" by the NRC, and placed on the on the NRC website list. Over and over again, between 1998 and 2000, the ACMUI membership expressed understanding and approval of the Working Group's revisions to the training and experience requirements.

Board certification should represent the best the respective field has to offer! Certification isn't for everyone. Certification should indicate that an individual has "gone the extra mile", not only to be the best they can be in their field, but to continue to strive to maintain that high level of overall competence in their chosen profession. Surely being board certified is worth more than just the ability to easily become an authorized user on a radioactive material license!

I perceive the currently listed boards did not pay attention to the revised training and experience requirements, so they are not prepared for the implementation of the new rule. I do not see this as a reason for changing the rule. I commend the Certification Board of Nuclear Cardiology for being attentive to the revised rule, and preparing for its implementation.

The following are my responses to the discussion topics.

1) Under the current Part 35, boards are not required to meet specific didactic/laboratory training and experience requirements to attain NRC recognition.

Response: As I stated above, when the training and experience requirements were revised during the 1980's, the intent was that the boards **would** meet the specified didactic/laboratory training and experience requirements to attain NRC recognition. However, this intent seems to have been forgotten over the years. The revised rule only reaffirms the old intent, leaving no doubt to a perspective board as to what radiation safety training and experience requirements they must have to attain NRC recognition.

2) Under the current rule, preceptor certification is not required for board certification. During the board certification process, the board makes its judgement that a candidate has satisfactorily completed the board's program and that the individual will be able to carry out the duties of this certification. Could another qualified

individual (e.g. a program director, a department head, or a professor) also sign the certification? In the case of the board certification process, can the members of the board collectively act as a "preceptor"?

Response: I again state that the intent of the current rule was that the boards require preceptor certification. I do not have a 1980's NRC definition for "preceptor", so I cannot say that the definition has not changed. In the revised rule, Preceptor is defined as "...an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer". Using this definition would not allow the boards to accept certification from a "qualified individual".

I believe that another individual can be allowed to sign on behalf of the actual preceptors. However, such an individual should be the preceptor's supervisor, such as a department head or program director, and a list of the preceptors should be included as reference.

I do not believe that members of the board, who have no personal knowledge of the "qualified individual", should be able to collectively act as a preceptor. I believe the "qualified individual" should be able to submit signatures of preceptors, or the preceptor's supervisor as specified in the previous paragraph, as part of their qualifications. The members of the board could decide to allow an individual to participate in any examination process without the individual submitting the necessary preceptor signatures. However, final certification should be withheld until the required preceptor signatures are submitted.

3) Board programs do not specifically include training and experience requirements for new modalities.

Response: It was the intent of the working group, in conjunction with recommendations from the ACMUI, that the training and experience requirements for other medical uses of byproduct material (emerging technologies) be handled on a case-by-case basis. No one can currently state what isotopes, chemical forms, physical forms, or routes of administration will fall into this area in the years to come. That is the reason the rule seems so vague. The intent is to make clear to the licensee what will be required of them to request licensed use of a new medical use not covered by the current rules. The example of a medical physicist with no experience in the use of

an HDR does not fall under this rule. Rather, it falls under 35.51. To try and tie down 35.1000 to something we are currently aware of has been pointed out as improper in public meetings. Specifically, the working group was using intravascular brachytherapy as an example of an emerging technology covered under this rule. Cardiologists and physicists pointed out that they do not consider intravascular brachytherapy an emerging technology. They consider it a current technology.

Existing qualified individuals wishing to use emerging technologies will have to submit information regarding the radiation safety hazards of the use to the NRC, and the NRC will then determine the necessary radiation safety training and experience requirements to become an authorized user, authorized medical physicist, etc.

Regarding the two options, my recommendation is as follows:

I believe the NRC should adopt Option 1, with two caveats. The ability of the Certification Board of Nuclear Cardiology to meet the revised requirements has proven that it can be done. However, the NRC could consider extending the old Subpart J training and experience requirements, as they are currently, until October 24, 2004. This gives the current boards another two years to meet the new requirements.

I also believe the NRC should allow the boards to accept another individual to sign on behalf of the actual preceptor, as long as the individual is the preceptor's supervisor, such as a department head or program director, and they submit a list of the preceptors as a reference.

Thank you for the opportunity to comment on this options paper. Should you have any questions, please feel free to contact me at 334-206-5391, or by e-mail at dwalter@adph.state.al.us.

Sincerely,

David Walter, Director
Radioactive Materials Licensing
Alabama Office of Radiation Control