RULEMAKING ISSUE
AFFIRMATION

January 19, 2005 SECY-05-0020

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: FINAL RULE: MEDICAL USE OF BYPRODUCT MATERIAL - RECOGNITION OF SPECIALTY BOARDS (RIN 3150-AH19)

PURPOSE:

To request Commission approval for publication, in the *Federal Register*, of a final rule to amend 10 CFR Part 35, "Medical Use of Byproduct Material," to modify training and experience (T&E) requirements for recognition of specialty board certification processes.

SUMMARY:

The final rule amends the regulations governing the medical use of byproduct material, to change requirements for recognition of specialty boards whose certification may be used to demonstrate the adequacy of the training and experience of individuals to serve as authorized users (AUs), authorized medical physicists (AMPs), authorized nuclear pharmacists (ANPs), or radiation safety officers (RSOs). The final rule also revises the requirements for demonstrating the adequacy of training and experience for the alternate pathway, and completes action on a petition for rulemaking filed on behalf of the Organization of Agreement States (OAS), PRM-35-17. The final rule provides a more flexible and performance-based approach to specifying requirements for training and experience, using a graded approach to ensure that training in radiation protection is consistent with the need for adequate understanding and skills. A regulatory analysis and environmental assessment have been completed to support this rule.

CONTACT: Roger Broseus, NMSS/IMNS
(301) 415-7608

BACKGROUND:

The current regulations in Part 35 offer three pathways for individuals to satisfy T&E requirements to be approved as an RSO, AMP, ANP, or AU. These pathways are: (1) approval of an individual who is certified by a specialty board, whose certification process has been recognized by the U.S. Nuclear Regulatory Commission (NRC) or an Agreement State as meeting the NRC's requirements for training and experience (a "recognized board"); (2) approval (e.g., identified on a license or permit) based on an evaluation of an individual's training and experience; or (3) identification of an individual's approval on an existing NRC or Agreement State license. For this discussion, pathway 1 will be referred to as the "certification pathway" and pathway 2 as the "alternate pathway."

During development of proposed and final rules for the current regulations in Part 35 [August 13, 1998 (63 FR 43516) and April 24, 2002 (67 FR 20249), respectively], it was generally believed that the specialty boards, whose certification processes were recognized by the NRC would meet, or could make adjustments to meet, the new requirements, established by that rulemaking, governing NRC recognition of specialty boards, and that they would continue to be recognized by NRC. However, when applications for recognition were received, the NRC staff determined that, except for one board, the boards did not meet all the requirements in the final rule for work experience and certification by a preceptor (i.e., an individual who provides, directs, or verifies training and experience) of completion of T&E and of competency to function independently as an RSO, AMP, ANP, or AU. To address the potential that individuals would no longer satisfy requirements for T&E under the certification pathway, the NRC modified the final rule by reinserting Subpart J of Part 35 (as contained in the proposed Part 35 rule) for a 2-year transition period, during which the NRC could work to ensure that appropriate requirements for T&E apply to recognition of specialty board certification processes. The Advisory Committee on the Medical Uses of Isotopes (ACMUI) and its subcommittee on T&E provided recommendations for an approach to revising requirements for T&E during the development of the rule. Membership on the subcommittee included the Agreement State member of the ACMUI. Subpart J of Part 35 provided for continuing recognition of the specialty boards, listed therein, during the transition period which was to end on October 24, 2004, as provided for in the current rule published on April 24, 2002. In order to ensure an effective transition, as discussed below, the effective date of Subpart J has been extended to October 24, 2005, under a separate rulemaking action (69 FR 55736, September 16, 2004).

In a Staff Requirements Memorandum dated October 9, 2003 (Attachment 1), the Commission approved publication of a proposed rule to amend the requirements for T&E in Part 35, "Medical Use of Byproduct Material" (SECY-03-0145, August 21, 2003). The proposed rule was published in the *Federal Register* on December 9, 2003 (68 FR 68549). The comment period closed on February 23, 2004, and 27 comments were received. Comments received from Agreement States, the public, and the ACMUI are discussed in detail in the *Federal Register* notice (FRN) (Attachment 2).

DISCUSSION:

Summary of Changes to Part 35.

The principal changes in regulations in the final rule relate to revising the criteria that a certification board must meet for its certification process to be recognized by the NRC or an Agreement State. Changes have also been made to requirements for T&E in the alternate pathway. The NRC staff implemented the direction from the Commission, in an SRM dated October 9, 2003, related to SECY-03-0145, to make various changes to the proposed rule before publication. In particular, the requirement for a preceptor statement was "decoupled" from requirements for recognition of specialty board certification processes (placing the requirement on the individual to obtain the preceptor statement) in the proposed rule, published in the *Federal Register* (December 9, 2003; 68 FR 68549). (This approach was followed in the final rule, as was the requirement for preceptor statements to be provided to the NRC by licensees, for approval of applications for individuals to serve as RSOs, AMPs, ANPs, or AUs.) Significant changes in the final rule, as compared to the proposed rule, are:

"Attest" and "attestation" are used in place of "certify" and "certification," in requirements for preceptor statements.

Agreement States are allowed up to 3 years to adopt the final rule.

The requirement, in 10 CFR 35.390(b)(1)(ii)(F), for experience with the elution of generators, testing, processing, and preparation of labeled radioactive drugs, is removed from 10 CFR 35.390. (The requirement in 10 CFR 35.390(b)(1)(ii)(C), for calculating, measuring, and safely preparing patient or human research subject dosages, is retained.)

The requirements for experience with oral and parenteral administrations of byproduct material for which a written directive (WD) is required, currently in 10 CFR 35.390(b)(1)(ii)(G), are removed from the requirements for recognition of specialty board certification processes. However, the regulations continue to require this experience for individuals to qualify as AUs for uses of byproduct material for which a written directive is required under 10 CFR 35.300 under the alternate pathway.

A new 10 CFR 35.396, entitled "Training for the parenteral administration of unsealed byproduct material requiring a written directive," is included in the final rule. This allows individuals who do not meet other requirements in 10 CFR 35.390(b)(1), to serve as AUs for parenteral administration of byproduct material for which a WD is required, if they meet the requirements in 10 CFR 35.396.

Requirements for individuals to serve as RSOs were changed, in 10 CFR 35.50, to include medical physicists who meet new requirements specified therein.

A requirement is added, for AUs in §§ 35.190, 35.290, and 35.390, and for ANPs in § 35.55, that training in basic radionuclide handling techniques must include a

minimum number of hours of classroom and laboratory ('didactic') training, for individuals to be approved as AUs and ANPs under the alternate pathway.

The final rule grants, in part, PRM-35-17 (Attachment 3) by incorporating requirements for minimum hours of classroom and laboratory ('didactic') training for ANPs and AUs under the alternate pathway in §§ 35.55, 35.190, 35.290, and 35.390.

The final rule provides for implementation of amendments by October 24, 2005.

These and other changes to the rule are discussed in more detail in the FRN (Attachment 2). The NRC staff believes that the final rule provides requirements that are less prescriptive than those in the current rule and allows for more flexible approaches by specialty boards in setting up their certification processes and requirements. The changes will also permit more flexibility in training programs that lead to certification, steps that will continue to ensure radiation safety while resulting in a reduction of regulatory burden.

Public Comments on Questions Posed Regarding the Proposed Rule.

The NRC posed the following questions in the *Federal Register* notice for the proposed rule (December 9, 2003; 68 FR 68549): (1) Do the proposed revisions to requirements for T&E experience provide reasonable assurance that RSOs, AMPs, ANPs, and AUs will have adequate training in radiation safety? (2) Should the word "attestation" be used in place of the word "certification," in preceptor statements? (3) Should Agreement States establish the requirements to conform with this proposed rule by October 24, 2005, or should they follow the normal process and be given a full 3 years to develop a compatible rule? Twenty-seven comments were received, in the form of letters and e-mails, from representatives of Agreement States, professional societies and certification boards, members of the medical community who may be affected by the amendments to requirements for T&E, and other members of the public. The ACMUI also provided comments on the proposed rule. Although many commenters offered specific recommendations related to question 1, commenters generally supported the proposed rule, and, in general, most comments reflected that the proposed requirements for T&E would be adequate to protect health and safety. Those commenters who offered opinions on question 2 generally supported using "attestation" in place of "certification" in preceptor statements, and the ACMUI's recommendation to make this change was adopted in the final rule. Several Agreement State commenters responded to question 3, and they generally advocated, as discussed below, that the NRC should allow Agreement States the full 3 years to adopt the final rule.

Consultation Process with the ACMUI.

During the transition period after publication of Part 35 on April 24, 2002 (67 FR 20249), the NRC worked with the ACMUI to develop a proposed rule on training and experience, and this final rule, both through ACMUI briefings of the Commission and through NRC/ACMUI meetings. Details of interactions with the ACMUI during the development of the proposed rule were discussed in SECY-03-0145. The staff continued consultations with the ACMUI, briefing the ACMUI on progress on the proposed rule on November 12, 2003. To facilitate public understanding and stakeholder review of proposed amendments to 10 CFR Part 35, the NRC staff posted a comparison document, with differences between the current and proposed rule

highlighted on the NRC's web site (on the rulemaking forum) on December 19, 2003. The NRC staff briefed the ACMUI about the status of the draft final rule and received comments from the ACMUI during its meeting on March 1-2, 2004. The ACMUI also briefed the Commission on March 2, 2004. The ACMUI held a publicly noticed meeting, via teleconference, on March 22, 2004, during which the proposed rule was discussed and additional comments on the proposed rule were provided to the NRC staff. The NRC staff also distributed draft implementation procedures to the ACMUI, for comment, during its meeting on November 12, 2003; and a draft revised NRC Form 313A (a form used to document training experience and to obtain a preceptor statement) was distributed for comment on December 20, 2003. Four ACMUI members, including the Agreement State representative, submitted comments on draft implementation procedures to the NRC staff on December 15, 2003; the ACMUI did not provide any comments on the revised draft NRC Form 313A.

During the public comment period on the proposed rule, Agreement State commenters proposed that requirements for a minimum number of hours of 'didactic' training should be added to §§ 35.55, 35.190, 35.290 and 35.390. The ACMUI's subcommittee on T&E was consulted to discuss resolution of this recommendation. The terms "didactic training" and "classroom and laboratory training" were used interchangeably by the Agreement States in their comments and both terms are used in the current regulations in Part 35. The term "classroom and laboratory" will be used hereinafter to refer to this type of training.

The NRC staff provided a draft of the final rule to the ACMUI and Agreement States on September 17, 2004, for a 30-day comment period. The draft final rule included the addition of a requirement for minimum hours of classroom and laboratory training for the alternative pathway to qualify as an ANP, in § 35.55, and for certain classes of AUs, in §§ 35.190, 35.290 and 35.390. The minimum number of hours proposed for classroom and laboratory training (applicable to the alternate pathway only) were as follows: § 35.55 – 200 hours; § 35.190 – 8 hours; § 35.290 – 80 hours; and § 35.390 – 200 hours.

The ACMUI held a public meeting (conducted as a teleconference), on October 5, 2004, to discuss the Agreement States' recommendation to require minimum numbers of hours of classroom and laboratory training. The NRC staff suggested that Agreement States be included in the teleconference. Approximately 37 representatives of 22 Agreement States participated in the call. The ACMUI also discussed the draft final rule and made recommendations during its public meeting held on October 13-14, 2004. During the meeting, the ACMUI agreed with the minimum number of hours of classroom and laboratory training specified in the draft final rule for the alternate pathway in §§ 35.55, 35.190, and 35.290 but passed a motion recommending that the minimum for classroom and laboratory training in § 35.390 be 80 hours instead of 200 hours.

After consultation with the ACMUI and the Agreement States, as discussed in more detail in the FRN (Attachment 2), the NRC staff determined that the final rule should include requirements for a minimum number of hours of classroom and laboratory training, applicable to the alternate pathway only, that is: § 35.55 – 200 hours; § 35.190 – 8 hours; § 35.290 – 80 hours; and § 35.390 – 200 hours. The NRC staff believes that this represents a graded approach (requiring more hours for more complex types of use), taking into account the risks associated with the activities conducted by nuclear pharmacists approved as ANPs under § 35.55 and AUs approved for medical uses of byproduct material under §§ 35.100, 35.200, and 35.300. This

approach ensures that training will be appropriately rigorous for those types of uses for which potential hazards are greater.

The ACMUI also passed a motion, at its meeting on October 13-14, 2004, recommending that medical physicists, who have been authorized to serve as medical physicists for high dose rate brachytherapy, gamma stereotactic radiosurgery, and teletherapy, be "grandfathered" (approved as an AMP) to serve as AMPs for those uses for which they are now responsible for regardless of whether they are currently listed on Agreement State or NRC licenses. Prior to the implementation of current regulations in Part 35 (published on April 24, 2002; 67 FR 20249), the NRC staff evaluated, on a case-by-case basis, the qualifications of individuals to perform the functions of medical physicists and identified them as AMPs on NRC licenses. These individuals are "grandfathered" under §35.57(a). Hence, the concern of the ACMUI would relate primarily to those medical physicists performing functions for licensees of Agreement States but who are not identified on Agreement State licenses. To "grandfather" (approve as AMPs) these medical physicists in an Agreement State, it is necessary to evaluate the training and experience of these individuals to serve as AMPs to ensure that they have achieved a level of radiation safety knowledge sufficient to function independently as an AMP for each type of medical unit for which the individual would be responsible. The NRC staff does not believe that it is appropriate to "grandfather" medical physicists to allow them to serve as AMPs, absent such an evaluation having been conducted. Regulatory agencies in some Agreement States have not been identifying those individuals who have been authorized to serve as medical physicists for the types of use which are of concern to ACMUI. Those regulatory agencies should identify (approve) medical physicists on licences and amendments for the types of use for which status as an AMP is required. This should include previously authorized medical physicists. These individuals, who have been identified on a license, would also be able to serve as preceptors for individuals to become AMPs.

Interactions with Agreement States.

The proposed and final rules were developed by a working group (WG) that included a representative from Alabama, nominated by the Organization of Agreement States (OAS). A representative from New York, nominated by the Conference of Radiation Control Program Directors (CRCPD) was added to the WG in June 2004. An Agreement State representative from Washington State, nominated by the OAS served on a Steering Group formed in June 2004. Representatives of Agreement States also provided comments on the proposed rule during the 75-day public comment period. These comments are discussed in the FRN for the final rule.

As noted above, the NRC staff provided a draft of the final rule to Agreement States and ACMUI on September 17, 2004, for a 30-day comment period. Agreement State comments related to the subject of specifying minimum numbers of hours of classroom and laboratory training and other matters such as the acceptability of the NRC not inspecting specialty boards but, rather, waiting to see if medical events occurred; the qualifications of preceptors, and whether a preceptor's authorization on a license is at risk when he signs a preceptor attestation. Discussion of these comments and NRC responses appear in the FRN (Attachment 2) under the heading, "Summary of Public Comments and Responses to Comments." Agreement State representatives participated in the ACMUI meeting, conducted as a teleconference on October 5, 2004. The NRC staff also distributed draft procedures for listing of recognized board

certifications to Agreement States on November 12, 2003. The NRC staff considered the Agreement State comments as the NRC developed the final procedures.

OAS Petition PRM-35-17.

The OAS filed a Petition for Rulemaking dated September 3, 2004 (PRM-35-17, Attachment 3) requesting that the NRC amend §§ 35.55, 35.190, 35.290 and 35.390 to define and specify the minimum number of classroom and laboratory training hours for AUs and ANPs identified in these sections. Notice of receipt of the petition was published in the *Federal Register* on October 28, 2004 (69 FR 62831). In the Federal Register notice, the NRC indicated that the issues raised in PRM-35-17 would be addressed in the current rulemaking and that the NRC would not be instituting a separate public comment period for this action.

The petition is granted, in part, by inclusion in the final rule of requirements for minimum numbers of hours of classroom and laboratory training, for the alternate pathway, in §§ 35.55, 35.190, 35.290, and 35.390. The final rule requires 8, 80 and 200 hours of classroom and laboratory training for 35.190, 35.290, and 35.55 and 35.390, respectively. The petition is denied in so far as the NRC is not requiring a minimum number of hours of classroom and laboratory training for the certification pathway. The NRC staff believes that, to do so, would unnecessarily limit the flexibility of boards to determine their certification requirements. The final rule only incorporates requirements for a minimum number of hours of classroom and laboratory training into the alternate pathway. This completes action on PRM-35-17.

Staff Approach to Determining Requirements for Minimum Hours of Classroom and Laboratory Training.

As explained above, during the ACMUI meeting on October 14, 2004, the ACMUI passed a motion recommending that the requirement for classroom and laboratory training, in § 35.390, be 80 rather than 200 hours. The ACMUI believes that the requirements for training in radiation safety and safe handling for medical uses under §§ 35.200 (no written directive required) and § 35.300 (written directive required), including the use of beta emitters, are similar. The total hours of training (classroom and laboratory, combined with work experience) is the same (700 hours) in §§ 35.290 and 35.390. Therefore, the ACMUI recommended that the number of hours required for classroom and laboratory training be the same as that required for § 35.290, i.e., 80 hours, because the knowledge required for radiation safety is similar for uses under both §§ 35.290 and 35.390. The ACMUI was also concerned that time taken for classroom and laboratory training required under § 35.390(b)(1)(I) would detract from time needed for training in other areas required of clinicians.

After consideration of both the ACMUI's and Agreement States' recommendations, the NRC staff analyzed the issue to determine the appropriate amount of classroom and laboratory training for approval of AUs under § 35.390. The NRC staff determined that 200 hours of classroom and laboratory training is the appropriate requirement for the alternate pathway in § 35.390 because more knowledge is necessary in the topic areas listed in § 35.390(b)(1)(i)(A) through (E), as enumerated below, to ensure the safe use of byproduct material for which a written directive is required.

1. Radiation physics and instrumentation – a wide variety of radionuclides, having a wider range of energies, both for beta and gamma emitters, is used. This affects understanding

of how radiation interacts with matter, which impacts understanding of shielding as well as the effects of radiation, and choice and use of instrumentation to detect and measure radiation and to measure quantities of radionuclides.

2. Radiation protection – more knowledge of principles and practices of radiation protection is needed because of the wider variety of radionuclides and associated types and energies of radiations used under § 35.300. Because greater quantities of byproduct material are commonly used for therapeutic purposes, risks are greater for patients and patient care personnel as well as for the public after the release of patients. Evaluation of these risks and associated protective measures and practices necessitates more knowledge for uses under § 35.300 than for uses under § 35.200. More knowledge of principles and practices in radiation protection is needed because of a wider variety of modes of administration and physical forms of byproduct material, e.g., intravenous, intra-peritoneal, oral and liquids in catheters. Each of these factors necessitates different radiation safety considerations for patients, occupationally exposed personnel and members of the public.

3. Mathematics pertaining to the use and measurement of radioactivity – Mathematics related to dosimetry is more complex for the wide variety of radionuclides, greater quantities, different types of radiation, and the broader purposes of use. Whereas byproduct material is used for diagnostic purposes under § 35.290, uses under § 35.390 are common for various therapeutic purposes.

4. Chemistry of byproduct material for medical use – a wide variety of chemical forms of byproduct material is used under § 35.300. These forms include ionic, bound-to-antibodies, and simpler chemical species, resulting in differences in uptake in the body and various organs and tissues (biodistribution), and elimination. Agents are used both for diagnostic and therapeutic purposes.

5. Radiation biology – more knowledge of radiation biology is needed because byproduct material are administered in greater quantities, both for diagnostic and therapeutic purposes, resulting in the potential for a greater variety of radiation effects and greater potential for harm. Risk assessments sometimes involve consideration of immediate biological effects whereas this is not usually a consideration in diagnostic applications under § 35.200.

In addition to these considerations, the NRC notes that new medical applications of byproduct material are evolving under § 35.300. Examples include more common use of byproduct material for alleviation of bone pain and for treatment of metastatic disease. This results in a need for additional knowledge of a wider variety of applications of physical and chemical forms of byproduct material.

OMB APPROVAL:

The NRC announced the availability of an Office of Management and Budget (OMB) supporting statement for a 30-day comment period in the *Federal Register* on December 2, 2003 (68 FR 67488). The OMB approved the proposed rule (OMB No. 3150-0010) and the related information collection (NRC Form 313A, OMB No. 3150-0120) on February 2, 2004. Submission of the final rule for clearance is not required.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication, in the *Federal Register*, the attached notice of final rulemaking (Attachment 2), which includes resolution of the OAS petition.

2. To satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b), certify that this rule, if promulgated, will not have significant impact on a substantial number of small entities. This certification is included in the attached *Federal Register* notice.

3. Note that:

   a. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).

   b. A final Regulatory Analysis has been prepared for this rulemaking (Attachment 4).

   c. A final Environmental Assessment has been prepared for this rulemaking; it appears in the attached notice of final rulemaking (Attachment 2).

   d. The staff has determined that this action is not a “major rule,” as defined in the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 [5 U.S.C 804(2)] and has confirmed this determination with the OMB. The appropriate Congressional and General Accounting Office contacts will be informed (Attachment 5).

   e. The appropriate Congressional committees will be informed of this action.

   f. The NRC staff will write a letter to the petitioner for PRM-35-17 to advise the petitioner regarding the disposition of the petition and provide a copy of the final rule.

   g. A press release will be issued by the Office of Public Affairs when the final rulemaking is filed with the Office of the Federal Register.

COORDINATION:

The Office of the General Counsel has no legal objection to the final rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

/RA Ellis W. Merschoff Acting For/

Luis A. Reyes
Executive Director
for Operations

Attachments:
1. SRM Dated October 9, 2003
2. *Federal Register* Notice
3. PRM-35-17
4. Regulatory Analysis
5. SBREFA Forms

October 9, 2003

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary **/RA by Andrew L. Bates Acting For/**

SUBJECT: STAFF REQUIREMENTS - SECY-03-0145 - PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL - RECOGNITION OF SPECIALTY BOARDS

The Commission has approved publication of the proposed amendments to Part 35 in the Federal Register subject to incorporation of the comments and changes noted below.

In addition, the Commission has approved the recommendation of the ACMUI concerning the preceptor statement which places the requirement on the individual to obtain the preceptor statement regardless of which training pathway is chosen. The staff should ensure that the proposed rule language is clear that a preceptor statement is required from individuals regardless of the training pathway chosen.

The Federal Register notice should be revised to:

1. Provide additional justification for the proposed rule changes to the "certification pathway." This needs to be done in the context that NRC has made a determination "that, except for one board, the boards did not meet all the requirements of the current rule. Specifically, the boards' certification programs failed to meet the requirements in the final rule regarding preceptor certification and work experience."

2. Add a separate section in the FRN that lists the questions that NRC is soliciting public comment on.

3. Include a question for public comment on whether commenters believe the revised requirements provide reasonable assurance that AUs, RSOs, AMPs, and ANPs will have adequate training in radiation safety.

4. Comment on the ACMUI's position that candidates "might bypass the board certification pathway ...." The Commission does not agree that the training and experience criteria in the current rule will result in candidates bypassing board certification. Board certification has been and will continue to be essential for practicing medicine. Staff's comments should recognize the difference needed for board certification for practicing physicians versus certification for an RSO, AMP, or ANP.

5. Provide a brief discussion on NRC's proposal for oversight of the boards. This

discussion should be consistent with the guidance in the SRM for SECY-02-0194 for monitoring trends in medical events that can be attributed to inadequate radiation safety training. Therefore, this discussion should address staff's plans to evaluate whether a medical event may have been due to inadequate radiation safety training related to the certification process, e.g., NRC's plans for assessing whether the examinations provided by the certifying boards adequately assess the knowledge/skills reflected in the proposed rule text.

6. Provide justification for adding the requirement for a degree in §35.50(a) and include a discussion that reinforces the Statements of Consideration for the final rule which noted that any individual, including a nuclear medicine technologist, who completes all of the training and experience requirements in the alternative pathway can be an RSO.

7. Provide the rationale for the change in the training criteria for authorized medical physicists in §35.51(a)(2).

8. Provide justification for deleting the minimum hour requirements in §35.490, "Training for use of manual brachytherapy sources," i.e., the requirements for 200 hours of classroom and laboratory training and 500 hours of work experience have been deleted.

9. Provide examples of what additional tests would be required under "quality control" that would not be required under "calibration."

10. To avoid confusion, provide a clear definition of what is meant by the different "rules" referenced in the FRN, e.g. the "draft final rule" referred to in paragraph 2 on page 4.

11. Standardize the language in the rule text, e.g. in §35.190(a)(1) it says to "meet the requirements" versus in §35.290(a)(1) it says to "satisfy the requirements."

12. In the Section by Section Analysis some of the rule changes were not discussed or were not fully justified. For example,
    §35.50, include the new requirement for a degree.
    §§35.390, 35.490 and 35.690, include the residency training

In addition, the following more specific changes need to be made to the FRN:

13. On page 3, the last sentence, provide the outcome of the discussions with the boards.

14. On page 7, last paragraph, second sentence, revise the sentence to read "The proposed rule would establish ~~separate~~ criteria for ~~that~~ a board ~~must meet~~ to be ...."

15. On page 10, last paragraph, revise line 2 to read ' ... to remove specific requirements ~~credit~~ for a degree in ....'

16. On pages 18 and 19, §§ 35.390 and 35.490, include the new requirement for review of the training programs.

17. On page 29, include a conforming change in §35.14 requiring the licensee to submit a copy of the preceptor statement as well as a copy of the board certification before permitting an individual to work as an AU, ANP, or AMP. Specifically, §35.14 should be

revised to state: “(a) A licensee shall provide the Commission a copy of the board certification and preceptor statement(s), the Commission or Agreement State license,...”

18. On page 39, §35.490(a)(2), revise the rule text to read “. . . clinical use of manual ~~high and low dose-rate~~ brachytherapy ... “

19. On page 41, §35.690(a)(2), revise the text to read “... radiosurgery, remote afterloaders ~~high and low dose-rate brachytherapy~~, and

cc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
CFO
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150-AH19

Medical Use of Byproduct Material – Recognition of Specialty Boards

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations governing the medical use of byproduct material to change its requirements for recognition of specialty boards whose certifications may be used to demonstrate the adequacy of the training and experience of individuals to serve as radiation safety officers, authorized medical physicists, authorized nuclear pharmacists, or authorized users. The final rule also revises the requirements for demonstrating the adequacy of training and experience for pathways other than the board certification pathway. This final rule grants, in part, a petition for rulemaking submitted by the Organization of Agreement States (PRM-35-17) and completes action on the petition.

EFFECTIVE DATE: This final rule is effective on [insert date 30 days after publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Roger W. Broseus, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone (301) 415-7608, email rwb@nrc.gov.

Supplementary Information:

I. Background.

During development of revised 10 CFR Part 35, published as a proposed rule on August 13, 1998 (63 FR 43516) and as a final rule on April 24, 2002 (67 FR 20249), there was a general belief that the boards, whose certifications were recognized by the NRC, would meet, or could make adjustments to meet, the new requirements established by that rulemaking governing recognition of specialty boards by the NRC and that the certifications of these boards would continue to be recognized by NRC. However, when applications for recognition were received, the NRC 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 (i.e., an individual who provides, directs, or verifies training and experience) attestation and work experience. The only board that currently meets the revised requirements is the Certification Board of Nuclear Cardiology (CBNC) because it developed its certification program based on the final rule (published on April 24, 2002 (67 FR 20249)).

The current regulations in 10 CFR Part 35 offer three pathways for individuals to satisfy training and experience (T&E) requirements to be approved as a radiation safety officer (RSO), authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), or authorized user (AU). These pathways are: (1) Approval of an individual who is certified by a specialty board whose certification has been recognized by the NRC or an Agreement State as meeting the NRC's requirements for training and experience (a "recognized board"); (2) Approval based on an evaluation of an individual's training and experience; or (3) Identification of an individual's approval on an existing NRC or Agreement State license. For this discussion, pathway (1) will be referred to as the certification pathway, and pathway (2) as the alternate pathway.

On February 19, 2002, in a briefing of the Commission, the Advisory Committee on Medical Uses of Isotopes (ACMUI[1]) expressed concern about requirements for T&E in the revised 10 CFR Part 35, approved by the Commission on October 23, 2000 (SRM-SECY-00-0118). The ACMUI was concerned that if the requirements for recognition of specialty board certifications were to become effective as drafted, there could be potential shortages of individuals qualified to serve as RSOs, AMPs, ANPs, and AUs because they would no longer meet the requirements for T&E under the certification pathway. The ACMUI indicated that, without changes to the requirements for T&E in the final rule approved by the Commission in October 2000, the boards would no longer be qualified for recognition by NRC and, therefore, a board's future diplomates could no longer be approved as RSOs, AMPs, ANPs, or AUs.

The ACMUI also expressed the concern that the boards might be "marginalized." Specifically, under the draft final rule, to gain approval via the certification pathway, a candidate for certification would have been required to meet all of the requirements in the alternate pathway, thereby imposing more requirements beyond those already required by boards, on candidates using the certification pathway for approval. The extra requirements of concern to the ACMUI, incorporated from the alternate pathway by reference, include a specification for length-of-training as well as obtaining a written attestation signed by a preceptor. Taken together with other requirements of boards, such as requiring candidates for certification to take written and/or oral examinations, the concern was that candidates seeking approval might bypass the board certification pathway and select the alternate pathway.

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[1] The Advisory Committee on the Medical Uses of Isotopes (ACMUI) advises NRC on policy and technical issues that arise in the regulation of the medical uses of radioactive material. The ACMUI membership includes a representative of Agreements States and health care professionals from various disciplines who comment on changes to NRC regulations and guidance; evaluate certain non-routine uses of radioactive material; provide technical assistance in licensing, inspection, and enforcement cases; and bring key issues to the attention of the Commission for appropriate action.

Based on these concerns, the ACMUI urged the Commission to implement measures to address the training and experience issues associated with recognition of specialty boards by the NRC in the draft final rule and to find a permanent solution after publication of the final rule. Subsequently, the NRC modified the final rule by reinserting Subpart J (as contained in the proposed rule before publication of revised Part 35 in April 2002) for a 2-year transition period. Subpart J provides for continuing recognition of the specialty boards listed therein during the transition period. The final rule was published in the Federal Register on April 24, 2002 (67 FR 20249), and became effective on October 24, 2002. As specified in § 35.10(c), the 2-year transition period ended on October 24, 2004. In a Staff Requirements Memorandum (SRM-COMSECY-02-0014) dated April 16, 2002, the Commission directed the NRC staff to develop options for addressing the training and experience issue. The intent was to have this final rule in place before the end of the 2-year transition period. Public comment on the proposed rule led the NRC to conclude that the transition period should be extended for 1 year to October 24, 2005, to allow time for implementation of amendments to requirements for recognition of specialty board certifications. This extension was effected through a separate rulemaking (69 FR 55736; September 16, 2004).

The issue in question concerns the requirements in the rule governing the recognition of specialty boards by the NRC. These requirements are located in the current regulations at §§ 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590, and 35.690.

The ACMUI submitted a report to the NRC on August 1, 2002 related to the T&E requirements. The NRC staff presented three options to the Commission in a Commission paper, SECY-02-0194, dated October 30, 2002, which included the recommendations of the ACMUI in an attachment. The three options were: (1) Retain the existing requirements in the current regulations; (2) Prepare a proposed rule to modify training and experience requirements

based on the recommendations submitted by the ACMUI; and, (3) The same as Option 2 with a minor modification (i.e., listing all specialty boards' certifications recognized by NRC on the NRC's web site rather than, as recommended by the ACMUI, listing some boards in the regulation and others on the web site). In SRM-02-0194, dated February 12, 2003, the Commission approved Option 3, directing the NRC staff to prepare a proposed rule based on the ACMUI's recommendations with certain exceptions. The Commission directed that a list of recognized board certifications be posted on the NRC's web site, that the preceptor statement remain as written in the current regulations (published April 24, 2002; 67 FR 20249), and that the staff should clarify that the preceptor language does not require an attestation of general clinical competency, but does require sufficient attestation to demonstrate that the candidate has the knowledge to fulfill the duties of the position for which certification is sought. This form of attestation should be preserved both for the certification pathway and the alternate pathway.

During a teleconference with the ACMUI, conducted on July 17, 2003, the ACMUI members continued to voice concern about having recognition of board certifications conditioned on requiring candidates for certification to obtain written attestation of competency signed by a preceptor. The ACMUI recommended that if the Commission still maintained that it was necessary to include a preceptor statement for all authorized positions named in 10 CFR Part 35, this requirement should be separated from the criteria for recognition of board certifications, as well as for the alternative pathway. Agreement State representatives participated in the teleconference and agreed with this recommendation. In a letter, dated July 23, 2003, the ACMUI recommended that the requirements for a preceptor statement be removed from the certification pathway; however, if the Commission still believed it necessary to include a preceptor statement for all "authorized positions" named in 10 CFR Part 35, the

ACMUI recommended that this requirement be separated from the board certification pathway and that it be specified separately as a new paragraph in each training section.

The NRC staff submitted a proposed rule to the Commission on August 21, 2003 (SECY-03-0145). The Commission approved the NRC staff's recommendation to publish the proposed rule, with certain changes directed by the Commission, in SRM-03-0145, dated October 9, 2003. The Commission approved the recommendation of the ACMUI that the requirement for a preceptor statement be removed from the requirements for recognition of specialty board certifications. The Commission also indicated it should be made clear in the proposed rule language that a preceptor statement is required regardless of which training pathway is chosen. The proposed rule was published for a 75-day comment period on December 9, 2003 (68 FR 68549). The NRC staff posted a comparison document, with differences between the current and proposed rule highlighted, on the NRC's rulemaking forum on December 19, 2003, to facilitate public understanding and stakeholder review of proposed changes to 10 CFR Part 35.

The ACMUI provided comments on the proposed rule at its meeting on March 1-2, 2004. The ACMUI also conducted a public meeting via teleconference on March 22, 2004, to discuss, in part, additional recommendations related to the proposed rule. Following receipt of public comments, the NRC staff distributed a draft final rule to ACMUI and Agreement States for their 30-day review and comment. The NRC considered the additional comments received in developing the final rule. These comments are discussed in Section IV, "Summary of Public Comments and Responses to Comments."

II. Petition for Rulemaking.

The Organization of Agreement States (OAS) (petitioner) filed a Petition for Rulemaking (petition) dated September 3, 2004 (PRM-35-17) requesting that the NRC amend §§ 35.55, 35.190, 35.290 and 35.390 to define and specify the minimum number of "didactic" training hours for Authorized Nuclear Pharmacists and Authorized Users identified in these sections. Notice of receipt of the petition was published in the Federal Register on October 28, 2004 (69 FR 62831). The terms "didactic training" and "classroom and laboratory training" were used interchangeably by the Agreement States in their comments and both terms are used in the current regulations in Part 35. The term "classroom and laboratory" will be used hereinafter to refer to this type of training.

The petitioner states that, in the current regulations in these sections, the minimum numbers of hours of classroom and laboratory training in radiation safety are not specified or separated from the total training hours. The petitioner notes that Subpart J does include a requirement for a minimum number of classroom and laboratory training hours as well as supervised work experience.

The petitioner asserts that the T&E requirements have been designated as "Category B" for Agreement State compatibility to provide nationwide consistency and uniformity of authorized user credentialing, and that the lack of clearly defined classroom and laboratory training hours for these authorized users weakens the consistency and uniformity of the rule. The petitioner also believes that the need for specified classroom and laboratory training hours is a radiation safety issue rather than a "practice of medicine" issue in that radiation safety for the patient and the occupational radiation workers may be compromised, and that a majority of radiation safety principles and procedures are learned during classroom and laboratory training.

As discussed further in subsequent sections of the **Supplementary Information,** during the 75-day public comment period for the proposed rule, ending on February 23, 2004, the NRC

received comments which raised the same issues as those raised by the petitioner. Because of the similarity in issues raised, the NRC has determined to consider the OAS petition as part of this rulemaking.

During resolution of the comments, the NRC staff consulted with the ACMUI and Agreement States on how to ensure adequacy of T&E in radiation safety and consistency of requirements for T&E between Agreement States and between Agreement States and the NRC. Agreement State representatives served as members on an NRC working group to develop this rule. A steering group, formed to provide recommendations to resolve the issue raised by the Agreement States related, during comments on the proposed rule, on requirements for classroom and laboratory training. The working group addressed issues raised in the petition related to specifying hours of classroom and laboratory training in 10 CFR Part 35. The NRC staff consulted with and received comments from the ACMUI via a public teleconference on the issue on October 5, 2004, with participation of Agreement States, and during its meeting on October 13-14, 2004. After consideration of the input from these sources, as well as review and analysis of the issue by the working and steering groups, the NRC has determined to grant the petition in part, and is revising §§ 35.55, 35.190, 35.290, and 35.390, in the final rule, to establish a requirement for minimum number of hours of classroom and laboratory training for the alternate pathway. The petition is denied, in part, in so far as the NRC is not requiring a minimum number of hours of classroom and laboratory training for the certification pathway. The NRC staff believes that such a requirement would unnecessarily limit the flexibility of boards to determine their certification requirements. The rationale for this change to requirements for T&E is explained in the NRC's response to comments on the proposed rule in Section IV. Summary of Public Comments and Responses to Comments,

under Part II – General Issues (Issue 1), and Part IV – Implementation by Agreement States – Timing and Compatibility (Issue 2).

This completes action on PRM-35-17.

III. Discussion.

The principal changes in the final rule involve revising the criteria for recognizing the certifications of specialty boards. These changes relate to the requirements for T&E that boards would place on candidates seeking board certification. The NRC staff reviewed board certification procedures and made a determination that, with one exception, the boards' certification programs failed to meet the requirements in the current regulations regarding preceptor certification (attestation) and work experience. This assessment[2] resulted from a detailed comparison, performed by the NRC staff, between requirements in the regulations (in Subparts B and D through H) and specialty board requirements for certification. The changes resulting from adoption of the final rule will resolve the issues related to recognition of board certifications by instituting requirements that are less prescriptive, while maintaining public health and safety. These changes will ensure that a clear regulatory determination can be made that specialty boards, both new and existing, meet the relevant criteria for recognition by the NRC or an Agreement State. Changes have also been made to the T&E requirements for the alternate pathway. The final rule provides a more flexible and performance-based approach

[2] "COMPARISON BETWEEN NRC REQUIREMENTS AND BOARDS' CERTIFICATION PROGRAMS," Attachment 2 to SECY-02-0194, "OPTIONS FOR ADDRESSING PART 35 TRAINING AND EXPERIENCE ISSUES ASSOCIATED WITH RECOGNITION OF SPECIALTY BOARDS BY NRC." SECY-02-0194 is available on the NRC's web site, www.nrc.gov, in the "Electronic Reading Room."

to specifying requirements for training and experience, using a graded approach to ensure that training in radiation protection is consistent with the need for adequate understanding and skills.

The changes to T&E requirements are intended to address issues raised by the ACMUI. However, the NRC disagrees with the ACMUI's belief that the T&E criteria in the current rule would result in candidates bypassing board certification. The NRC believes that board certification has been, and will continue to be, essential for physicians, including AUs, to practice medicine. While health physicists, medical physicists, nuclear pharmacists, and physicians can serve in the respective categories of RSO, AMP, ANP, and AU by satisfying T&E requirements under the alternate pathway, the NRC believes that individuals who would have sought certification are likely to continue to do so because certifications are useful to individuals for reasons other than satisfying requirements in 10 CFR Part 35, e.g., measuring areas of competence that go beyond regulatory requirements established under the Atomic Energy Act. Furthermore, some State agencies now require that individuals be certified by specialty boards before they can practice in some specialties, e.g., as medical physicists and nuclear pharmacists.

Changes to the Certification Pathway.

For the certification pathway, the current regulations incorporate the more prescriptive requirements from the alternate pathway. This final rule establishes less prescriptive criteria for board certifications to be recognized by the NRC or an Agreement State.

For the RSO, AMP, and ANP, the revised criteria include a degree from an accredited college or university, professional experience, passing an examination administered by the board, and in some cases, additional training related to the type of use for which an individual

would be responsible. The requirement for passing an examination reflects the current practice of certification boards.

The addition of a requirement in § 35.50(a) for candidates for RSO to have a degree is consistent with current standards of certification boards to require a minimum of a baccalaureate degree. The NRC believes that this requirement helps ensure that a candidate for RSO has the level of knowledge necessary to fulfill the duties of an RSO. However, this final rule retains current regulatory provisions that allow candidates who do not hold a degree required under revisions to § 35.50(a) to qualify for positions as RSO under provisions in § 35.50(b). Requirements for T&E of candidates to serve as AMPs have been revised for the board certification pathway, in § 35.51(a)(2), to require 2 years of full-time practical training and/or supervised experience under the supervision of a medical physicist certified by a specialty board, whose certification is recognized by the NRC or an Agreement State, or in clinical radiation facilities providing high-energy, external beam therapy and brachytherapy services under the direct supervision of physicians who meet the requirements for AUs in §§ 35.400 or 35.600 or under supervision of a certified medical physicist in clinical radiation facilities. This T&E will help ensure that candidates have the level of knowledge necessary to fulfill the duties of an AMP.

The current regulations in 10 CFR Part 35 provide for a preceptor, defined in § 35.2, to certify that individuals have satisfactorily completed requirements for T&E and have achieved a level of radiation safety knowledge sufficient to function independently as RSOs, AMPs, ANPs, and AUs. In response to public comments, as discussed under the heading “IV. Summary of Public Comments and Responses to Comments,” the NRC is now using “attestation” and “attest” in place of “certification” and “certify” in 10 CFR Part 35. A preceptor attestation is commonly referred to as a “preceptor statement,” and this term is used interchangeably with the

term “preceptor attestation” in the **Supplementary Information**, particularly in the summary of public comments, to reflect this usage by commenters.

The requirement that boards must have candidates for certification obtain a preceptor attestation as a condition for NRC recognition of certifications has been removed in the final rule; however, individuals are still required to obtain preceptor attestations, and licensees are required to submit them to the NRC (except as provided in § 35.15(d)). This is an addition to the current requirement in § 35.14(a) to provide a copy of board certifications to the NRC. Further discussion of the requirement for a preceptor attestation appears under the heading “Preceptor Attestation.” The certification pathway also includes a specification for the number of hours of training and experience for ANPs and AUs for certain uses of byproduct material under §§ 35.100, 35.200, 35.300 (in §§ 35.390, 35.392, 35.394, and 35.396 for uses under § 35.300), and 35.500. The ACMUI recommended, for the proposed rule, that the requirement for 200 hours of classroom and laboratory training, now required in §§ 35.490 and 35.690, be removed because it believes that the combination of degree, practical experience, and examination in the criteria for recognizing certifying boards is equivalent to the number of hours of classroom and laboratory training specified for the alternative pathway. A detailed analysis of T&E requirements was performed by NRC staff and appears as Attachment 1 to SECY-02-0194, "OPTIONS FOR ADDRESSING PART 35 TRAINING AND EXPERIENCE ISSUES ASSOCIATED WITH RECOGNITION OF SPECIALTY BOARDS BY NRC.” The NRC believes that, although the requirements are not identical, the T&E standard for recognizing certifying boards will be equivalent to the standard for the alternate pathway. The board certification process requires a candidate to have an academic degree, complete practical experience or a residency program, and pass an examination. Examinations test the knowledge and skills required to perform the applicable activities, including those in

§§ 35.490(a)(2) and 35.690(a)(2), to ensure radiation safety. The NRC believes that the combination of a degree, practical experience, and an examination, in the criteria for recognizing certifying boards, will be equivalent to the number of hours of classroom and laboratory training specified for the alternate pathway. Further, the requirement in the certification pathway for §§ 35.490 and 35.690 for completion of an approved residency program, provides added assurance that T&E is sufficient. Therefore, the requirement for 200 hours of classroom and laboratory training does not apply to the criteria for recognition of board certification processes in §§ 35.490, and 35.690 of the final rule.

The ACMUI's recommendations included the addition of the Royal College of Physicians and Surgeons of Canada (RCPSC) in listings of entities which approve residency training to satisfy requirements for the board certification pathway for uses under §§ 35.300, 35.400, and 35.600. While the RCPSC was named in Subpart J of the current rule, it is not named in other subparts. There are reciprocal arrangements between U.S. entities and the RCPSC regarding approval of residency programs. Thus, the NRC finds these reciprocal agreements to be a sufficient basis to provide that RCPSC be included in various sections of 10 CFR Part 35.

The final rule provides the boards more latitude in making the determination that individuals are fully trained and capable of performing their duties involving radiation safety. These changes to the certification pathway continue to ensure the safe use of byproduct material by medical licensees by establishing criteria for specialty boards to use in granting certifications. The NRC made a determination that, with the exception of one specialty board, the boards do not meet the requirement in the current rule regarding preceptor certification and work experience. With more latitude under the certification pathway in the final rule, the NRC believes that boards will be able to meet the revised requirements for recognition of board certification processes.

Changes to the Alternate Pathway.

The final rule also contains revised requirements for some of the alternate pathways. Some of these changes are minor and clarify the requirements for T&E.

The ACMUI's recommendations for approval as an AU in the alternate pathway in §§ 35.490(b) and 35.690(b) include the addition of the RCPSC to the listings of organizations that approve residency programs. The NRC finds that RCPSC should be included in the listing for the reasons previously discussed under the heading, "Changes to the Certification Pathway."

In comments on the proposed rule, Agreement States recommended that a minimum number of hours of 'didactic' training in basic radionuclide handling techniques should be specified for individuals to qualify as ANPs under § 35.51 and as AUs under §§ 35.190, 35.290, and 35.390. The NRC understands that references by Agreement States to "didactic training" refers both to the "didactic training," currently required to qualify as an authorized nuclear pharmacist under current regulations in § 35.55(b)(1)(i), as well as the "classroom and laboratory training" required to qualify as an authorized user in §§ 35.190(c)(1)(i), 35.290(c)(1)(i) and 35.390(b)(1)(i). The term "classroom and laboratory training" will be used hereinafter to refer to this type of training. As discussed in Part II, Issue 1, and Part IV, Issue 2, of the Summary of Public Comments, the final rule specifies minimum number of hours of classroom and laboratory training for the alternate pathway.

Training Specific to Type of Use.

The ACMUI recommended that, in addition to meeting minimum T&E requirements, authorized individuals should have training or experience in the use of byproduct material or specific modalities (types of use), as appropriate, for which a licensee is authorized. The

ACMUI also recommended that the requirement apply to newly hired, authorized individuals and when a new type of use is added to the licensee's program. The NRC supports these changes, believing that they will ensure that a licensee's staff has adequate knowledge and experience to fulfill the duties for which they are responsible. The final rule includes new paragraphs that add this requirement in § 35.50(e) for RSOs, § 35.51(c) for AMPs, and for AUs in § 35.690(c) for remote afterloader, teletherapy and gamma stereotactic radiosurgery units. For uses under § 35.300, requirements in §§ 35.390(b)(1) and § 35.396(d) provide for training specific to type of use which applies to both the board certification and alternate pathways.

Other Changes.

In the current regulations, § 35.390(b)(1)(ii)(G) specifies that work experience for uses of byproduct material in unsealed form, for which a written directive (WD) is required, must include administering dosages of radioactive drugs involving a minimum of three cases in each of the categories for which the individual is requesting authorized user status. Sections 35.390, paragraphs (b)(1)(ii)(G)(1), (3) and (4) refer to oral and parenteral administration of certain radionuclides. The final rule clarifies that this training must be with quantities of radionuclides for which a WD is required. The NRC believes these changes are necessary because, without them, an individual might cite experience with low-level dosages to satisfy requirements for work experience; the changes place emphasis on the need for AUs to have work experience with higher level dosages, for which a WD is required. Similar requirements have also been incorporated into new § 35.396(d).

The ACMUI and public commenters on the proposed rule stated that the physicians, who have sufficient T&E to serve as AUs for the medical use of unsealed byproduct material for which a WD is required, are unable to meet the requirements for use in Subpart E. As

discussed in response to public comments on § 35.390, this issue was resolved by the inclusion of a new § 35.396, entitled, “Training for the parenteral administration of unsealed byproduct material requiring a written directive.” A conforming change was also made to § 35.8, “Information collection requirements: OMB approval,” to indicate that an information collection requirement applies to § 35.396.

The ACMUI recommended that the requirements for work experience for authorized users in §§ 35.190, 35.290, and 35.390 be changed to require experience with performing quality control check of instruments rather than with calibrating instruments. In addition to instrument calibration, quality control procedures commonly include checks of parameters such as linearity, constancy, and functionality (including battery checks). The NRC agrees with the ACMUI’s recommendation because ensuring proper function of these instruments involves more than periodic calibration. The final rule effects these recommendations with changes to §§ 35.190(c)(1)(ii)(B), 35.290(c)(1)(ii)(B), 35.390(b)(1)(ii)(B), 35.392(c)(2)(ii), and 35.394(c)(2)(ii). Similar requirements have also been incorporated into new § 35.396(d)(2).

Training requirements for authorization as a medical physicist have been changed in § 35.51(b)(1) to remove specific requirements for a degree in biophysics, radiological physics, and health physics, and add the more general, other physical sciences, as well as engineering and applied mathematics. The requirement for 1 year of full-time training in therapeutic radiological physics has been changed to a more general requirement for 1 year of full-time training in medical physics. In § 35.690(b)(2), the requirement for candidates to be approved as AUs has been changed to broaden the requirement that supervised clinical experience be received in “radiation therapy” rather than in “radiation oncology.” These changes are needed to allow for the therapeutic use of byproduct material in applications other than cancer therapy.

Current regulations in § 35.50(c) provide that an AMP identified on a licensee's license can serve as an RSO, provided that the individual has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has responsibilities as an RSO. However, current regulations only require services of an AMP for uses under §§ 35.433 and 35.600; a few AMPs are also named on licenses for uses under § 35.1000. Therefore, individuals who may have adequate T&E to serve as AMPs for types of use licensed under §§ 35.100, 35.200, 35.300, 35.400 and 35.500, are not listed on an NRC or Agreement State license under current rules. Medical physicists who are certified by a specialty board whose certification is recognized by the Commission or an Agreement State have training and experience in radiation safety aspects of the use of byproduct material for medical purposes. The regulations in § 35.50 have been changed to allow medical physicists, who are certified by a specialty board whose certification is recognized by the NRC or an Agreement State, to serve as RSOs, while retaining the requirement that these individuals have experience specific to the types of use for which they would be responsible. This change removes an impediment for individuals who have adequate T&E to become approved as RSOs. It also avoids placing a burden on licensees to apply for an exemption to regulations and on NRC and Agreement State staff who would be required to process an application for an exemption to regulations to approve a licensee's request to have a medical physicist, certified by a specialty board whose certifications are recognized by the NRC, serve as an RSO. Comments on the proposed rule indicated that medical physicists generally have adequate T&E to serve as RSOs. As discussed in response to comments on § 35.50, this section has also been amended to provide criteria for medical physicists, other than those who are AMPs, to serve as RSOs.

The term "high-energy" is used in the rule text in §§ 35.51(a)(2)(ii) and 35.51(b)(1) to specify the type of training to be included in T&E for AMPs. High-energy radiation is specified, in §§ 35.51(a)(2)(ii) and 35.51(b)(1) of the final rule, as photons and electrons with energies

greater than or equal to 1 million electron volts, which is consistent with the definition of high-energy used by the International Commission on Radiation Units and Measurements in Report 42, Use of Computers in External Beam Radiotherapy Procedures with High-Energy Photons and Electrons.

In § 35.75(a), reference is made to "draft" licensing guidance in NUREG-1556, Vol. 9. This guidance was published in final version in October 2002. Therefore, the "draft" designation is being removed.

Preceptor Attestation.

Part 35 currently requires a written certification, termed attestation in this final rule (and referred to as attestation in this discussion, when appropriate), that the individual has satisfactorily completed the required training, has achieved a level of knowledge or competency sufficient to function independently, and requires that the written certification be signed by a preceptor who is a radiation safety officer, authorized medical physicist, authorized nuclear pharmacist or authorized user. This requirement applies to both the board certification and alternate pathways.

The ACMUI recommended that, instead of certifying "competency," the preceptor should attest that the individual has satisfactorily completed the required training and experience. It further recommended that a training program director be allowed to sign the written attestation.

As explained previously, the Commission considered recommendations of the ACMUI and determined in SRM-02-0194, "OPTIONS FOR ADDRESSING PART 35 TRAINING AND EXPERIENCE ISSUES ASSOCIATED WITH RECOGNITION OF SPECIALTY BOARDS BY NRC," that the preceptor statement should remain as written in the current regulations. However, the Commission emphasized that the preceptor language does not require an attestation of general clinical competency, but requires sufficient attestation to demonstrate that

the candidate has the knowledge to fulfill the duties of the position for which certification is sought.

The ACMUI also recommended that the Commission separate the requirement to obtain a preceptor statement from the certification and alternate pathways, and to specify this requirement as a new paragraph in the sections dealing with T&E for RSOs, AMPs, ANPs, and AUs. The Commission approved this recommendation of the ACMUI, placing the requirement on licensees to submit the preceptor statements to the NRC. This requirement appeared in the proposed rule. The regulations retain the requirements that individuals obtain preceptor attestations for both the certification and alternate pathways.

The requirement for licensees to submit a preceptor attestation to the NRC appears in revised § 35.14(a).

Listing of Recognized Board Certifications.

The NRC will list on its web site (http://www.nrc.gov), instead of in its regulations, the names of board certifications for those boards whose certification processes meet the NRC's requirements. This approach has the advantage of eliminating the need to amend 10 CFR Part 35 to effect recognition each time a new board needs to be added to the listing. The ACMUI and specialty board representatives who participated in a public meeting on May 20, 2003, were in agreement with this approach.

Because of the importance of board certification in establishing the adequacy of T&E for individuals to serve as RSO, AMPs, ANPs, and AUs, a clear regulatory determination must be made that all boards, both new and existing, meet the relevant regulatory criteria. Evaluation of board requirements against revised criteria in the final rule is necessary to make this determination. Boards that are currently listed in Subpart J of Part 35 and other boards are

required to apply for recognition under this rule. When necessary, the NRC staff will review a board's submittal with the ACMUI before a decision on recognition of a board is made.

The NRC will place the procedures for listing and delisting of specialty boards on its web site at the time of publication of the final rule. Because of the important role of board certification, the procedures will provide for making a clear regulatory determination that boards, both new and existing, meet the relevant criteria in the revised regulations. The procedures provide for both adding new specialty boards to the listing of recognized certifications and for removal from the list.

The NRC staff does not intend to conduct inspections of the specialty boards whose certification processes it recognizes but will monitor trends in medical events. If the NRC staff determines that a series of medical events is associated with a particular specialty, and the trend can be attributed to inadequate radiation safety training, the staff will determine whether the inadequate training is related to a deficiency in a board's evaluation of the radiation safety competency of the board's diplomates. The NRC conducts a comprehensive regulatory program to ensure safety. This regulatory program is also important to the identification of issues related to T&E that may, in turn, point to issues associated with the certification process of a specialty board. If these activities result in identification of a deficiency in a board's evaluation of the radiation safety competency of the board's diplomates, the NRC staff will review the specialty board's certification program. The assessment will include a determination of whether the board's examination adequately assesses the requisite knowledge and skills in radiation safety. If the staff determines that changes in the board's evaluation of competency in radiation safety are necessary, and the board either cannot or will not make adequate changes to its program to address these needs, then the NRC will withdraw recognition of that specialty board's certification processes and delist that board. The NRC staff will inform the Commission and the ACMUI of an NRC staff decision to withdraw recognition. The NRC has reviewed

existing procedures for the conduct of inspections and has determined that they provide for collection of the information necessary to evaluate trends in medical events possibly related to requirements for T&E of specialty boards. The NRC staff provided a copy of draft plans for implementation of the procedures for listing and delisting of board certifications to Agreement States and the ACMUI during the development of the proposed rule. The comments provided by these groups were considered by the NRC staff in developing final procedures for implementation.

Stakeholder Interactions.

On May 20, 2003, a public meeting was held to solicit early input on the proposed rule from representatives of professional specialty boards and other interested stakeholders. The NRC staff also made a presentation to the ACMUI on May 20, 2003, regarding the staff's approach to the proposed rule. The ACMUI provided input and a comment was received via email from a participant in the meeting with the boards.

The proposed rule was published in the Federal Register on December 9, 2003 (68 FR 68549). The NRC staff briefed the ACMUI on the proposed rule during its meeting on March 2, 2004, and received comments from the ACMUI on the proposed rule during this meeting and a public teleconference conducted on March 22, 2004. Comments of the ACMUI, Agreement States, board members, and members of the public provided useful information to the NRC in preparing the proposed and final rule. A person from the State of Alabama, nominated by the Organization of Agreement States, participated as a member of the working group with the NRC staff in the development of the proposed and final rule. A person from the State of New York, nominated by the CRCPD, was added to the working group and participated in the resolution of comments on the proposed and draft final rule. The NRC staff distributed a draft final rule to the Agreement States and the ACMUI for 30-day review, ending on

October 18, 2004. During this time, the ACMUI held a publicly announced meeting, via teleconference, on October 5, 2004, with Agreement State participation, to discuss requirements for a minimum number of hours of classroom and laboratory training in §§ 35.55, 35.190, 35.290, and 35.390. The meeting was announced in the Federal Register on September 28, 2004 (69 FR 57977). Approximately 37 representatives of 22 Agreement States participated in the meeting. The ACMUI also discussed the draft final rule, and made recommendations to the NRC, during its meeting on October 13-14, 2004. These comments are discussed in Section IV. Summary of Public Comments and Responses to Comments.

Additional Recommendations of the ACMUI.

At the teleconference held on July 17, 2003, the ACMUI discussed the draft proposed rule; Agreement State representatives also participated in the teleconference. During the teleconference, the ACMUI agreed with the NRC staff recommendation to broaden the requirement that supervised clinical experience be received in a "radiation facility" rather than in a "radiation oncology facility" for individuals to qualify as AMPs, in § 35.51(b)(1) of the proposed rule, and to change the requirement for experience in "radiation oncology" in § 35.690(b)(2) to allow for experience in "radiation therapy." Parallel changes were made to the certification pathway for AMPs in the proposed rule in § 35.51(a)(2)(ii) and in § 35.690(a)(1) for uses under § 35.600. These changes were retained in the final rule.

The ACMUI recommended that the requirements for experience, described in the current rule in § 35.390(b)(1)(ii)(G), not be included in criteria for recognition of specialty board certifications, but that they continue to be required for AUs meeting T&E requirements for both the certification and alternate pathways. This recommendation was not incorporated into the proposed rule, because the NRC staff believed that the requirements for work experience in § 35.390(b)(1)(ii)(G) are essential for an individual to be able to function independently as an

AU for administration of byproduct material for which a WD is required. As discussed in the response to public comments on the proposed rule, the ACMUI raised this recommendation again, indicating that many individuals obtain the experience required in § 35.390(b)(1)(ii)(G) after they have obtained their board certification. After further consideration, the requirement for this experience was removed from requirements for recognition of board certifications in the final rule but retained as a requirement for individuals to be AUs.

At the teleconference held on March 22, 2004, the ACMUI recommended removal of requirements, in § 35.390(b)(1)(ii)(F), for experience with elution of generators and measuring, testing, and preparation of radiolabeled drugs. As indicated in the discussion of public comments on § 35.390, this requirement has been removed from this section in the final rule but retained in other sections when individuals qualify as AUs by virtue of being approved as an AU under § 35.390. Additional recommendations, made by the ACMUI during the meeting on October 13 - 14, 2004, are discussed in Section IV. Summary of Public Comments and Responses to Comments.

Timing of Agreement State Implementation.

Normally, Agreement States have 3 years in which to adopt a compatible rule. Agreement States have until October 24, 2005, to adopt the revised 10 CFR Part 35 published on April 24, 2002. It was noted in the **Supplementary Information** for the proposed rule that, for Agreement States to adopt the proposed training and experience requirements and have them in place by October 24, 2005, the Agreement States would have a shortened time frame for developing compatible requirements. Because Agreement States had voiced concern regarding this shortened time frame, the NRC invited public comment on this issue. As indicated in “IV. Summary of Public Comments and Responses to Public Comments,” the NRC is allowing 3 years for adoption of this final rule.

Revision of Guidance for Licensing of Medical Use of Byproduct Material.

Licensing guidance for medical uses of byproduct material is available in NUREG-1556, Vol 9, "Consolidated Guidance About Materials Licenses. Program-Specific Guidance About Medical Use Licenses." The NRC has revised this guidance to conform to the revisions in this final rule and is making it available to the public coincident with publication of the final rule.

Extension of Subpart J to October 24, 2005.

The NRC has extended the expiration date for Subpart J to October 24, 2005, through a separate rulemaking (69 FR 55736, September 16, 2004).

IV. Summary of Public Comments and Responses to Comments.

The NRC received 27 comments on the proposed rule. The commenters included members of the general public and the ACMUI as well as representatives of Agreement States, professional societies, and certification boards. Additional comments from Agreement States were received on a draft of the final rule distributed made available to Agreement States for a 30 day comment period, ending on October 18, 2004. Copies of the public comments are available for review in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD.

This section summarizes the written and oral comments received and provides responses to these comments. Part I contains a list of the acronyms used in this section. Part II contains a discussion of general issues that were considered during the rulemaking. Part III contains a discussion of comments on specific sections in the proposed rule. Comments on timing of adoption of the rule by Agreement States and compatibility are discussed in Part IV.

The NRC posed three questions in the "Invitation for Public Comment on Specific Issues" section of the proposed rule. These questions were:

1. Do the proposed revisions to requirements for training and experience provide reasonable assurance that RSOs, AMPs, ANPs, and AUs will have adequate training in radiation safety? (This question is discussed in Part II – General Issues, Issue 1.)

2. Should Agreement States establish the requirements to conform with this proposed rule by October 24, 2005, or should they follow the normal process and be given a full 3 years to develop a compatible rule? (This question is discussed in Part IV – Implementation by Agreement States – Timing and Compatibility.)

3. Should the word "attestation" be used in place of the word "certification" in preceptor statements? (This question is discussed in Part II – General Issues, Issue 2.)

Part I – Acronyms

The following acronyms are used in the discussion of both the general and specific comments.

ACGME	Accreditation Council for Graduate Medical Education
ACMUI	Advisory Committee on the Medical Uses of Isotopes
ACPE	American Council on Pharmaceutical Education
ABMS	American Board of Medical Specialties
AMP	Authorized medical physicist
ANP	Authorized nuclear pharmacist
AU	Authorized user
FPGEC	Foreign Pharmacy Graduate Examination Committee

NMED	Nuclear Materials Events Database
OAS	Organization of Agreement States
RSO	Radiation safety officer
T&E	Training and experience
WD	Written directive

Part II – General Issues

Several commenters expressed general support for the proposed rule as well as offering comments on specific aspects of the proposed rule, which are discussed further in succeeding sections. Support was also voiced for the listing of recognized board certifications on the NRC's web site rather than in regulations.

Issue 1: Do the proposed revisions to requirements for training and experience (T&E) provide reasonable assurance that RSOs, AMPs, ANPs, and AUs will have adequate training in radiation safety?

Comment: One commenter suggested that the NRC should go back to its original preceptor concept, under which no board certifications were required, but the preceptor (mentor) had the responsibility to ensure that training was adequate to ensure health and safety and medical efficacy. The commenter expressed concern that applicants could receive certification without complete knowledge and skills in a particular discipline, i.e., board certification may omit or excuse lack of knowledge and skill (if the applicant passes the requisite examination with a score of less than 100 percent) where the alternate pathway would require demonstration of 100 percent in a given discipline.

Response: The NRC believes that RSOs, AMPs, ANPs, and AUs should have T&E sufficient to ensure radiation safety in the medical use of byproduct material. The NRC believes that it is necessary to specify requirements for T&E to accomplish this objective, either by requiring that candidates for approval as RSOs, AMPs, ANPs, or AUs are certified by a board which has a certification process that has been recognized by the NRC, or by meeting the requirements for T&E for the alternate pathway, combined with attestation by a preceptor that the individual has satisfactorily completed these requirements and has achieved a level of competency sufficient to function independently in the position for which approval is sought. The NRC believes that requirements for both pathways are similarly and sufficiently rigorous, and, that by passing a board examination, together with meeting the other requirements in the board certification pathway, a candidate will have demonstrated the knowledge and skill necessary to safely handle byproduct material. The NRC believes that this combination of requirements will ensure the safe medical use of byproduct material and has retained the option for AUs to meet requirements for T&E via the certification pathway.

Comment: One commenter indicated, given that new problems consistently arise, specialty board training should only be accepted if it can be shown that there is a recertification/required continuing education every 10 years or less and that the recertification/continuing education process can be shown to encompass the radiation protection aspects of newer technologies.

Response: The NRC plans to periodically review the requirements of boards for certification to accommodate changing needs for T&E. However, the NRC does not depend solely on board certification to ensure adequacy of T&E. The regulations also provide, in § 35.59, that T&E must have been obtained within 7 years preceding the date of an application to the NRC or that the individual had related continuing T&E. They also provide, in § 35.57, for accommodating experienced AUs (e.g., individuals identified on a license), allowing those who

serve as AUs under existing licenses and permits to continue medical uses for which they have been authorized. NRC regulations also provide requirements for licensing of new medical uses of byproduct material, including assessment of the adequacy of T&E of AUs for proposals for new uses in requests for amendments to licenses.

Comment: One Agreement State commenter on the draft final rule stated that the NRC appears to want only limited submittal of the training programs for review and approval from medical boards and does not plan to conduct inspections of specialty boards to insure that they meet the latest certification requirements. Rather, the intent is to wait and see if specific medical events related to training occur in the field before investigating. The commenter does not believe this is acceptable, especially when considering the number of hospital staff and patients that may be at risk before this type of link to training can or will be made once an incident occurs.

Response: In order to have their certification processes recognized, specialty boards must demonstrate that their certification processes meet the specific criteria established in the regulations. The NRC will carefully review the documentation submitted before recognizing a board's certification program. The NRC believes that this process for board recognition, taken together with the NRC's coordination with ACMUI, its inspection of licensed facilities, and its continued monitoring of medical events, will be sufficient to ensure public health and safety.

Comment: Commenters from Agreement States expressed concern that the regulations no longer specify the number of classroom and laboratory or supervised clinical and work hours necessary for the various types of use. One commenter indicated that this could jeopardize radiation safety, and recommended that the NRC include a minimum acceptable number of hours of classroom and laboratory training in the **Supplementary Information** for the final rule (i.e., a minimum of 200 hours of classroom and laboratory training out of the total of 700 hours for those types of use for which a WD is required (§ 35.390); 80 hours of classroom and

laboratory training for those uses for which a WD is not required but for which 700 hours is still required (§ 35.290); and a minimum of 8 hours of classroom and laboratory training for types of use for which 60 hours of training is required (§ 35.190)), based on the risk to patients, occupational workers, and the public, for each type of use, and assuming class days are 8 hours. Three other commenters from Agreement States recommended that regulatory agencies should specify a minimum number of hours of classroom and laboratory training under §§ 35.190, 35.290, and 35.390. One commenter suggested that individuals qualifying as ANPs under § 35.55 and as AUs under § 35.390 should be required to have 200 hours of classroom and laboratory training. Also, the Organization of Agreement States (OAS) (petitioner) filed a Petition for Rulemaking (petition) dated September 3, 2004 (PRM-35-17) requesting that the NRC amend §§ 35.55, 35.190, 35.290 and 35.390 to define and specify the minimum number of didactic training hours for Authorized Nuclear Pharmacists and Authorized Users identified in these sections.

Response: The NRC agrees with the Agreement States' assertion that the inclusion of a requirement for minimum number of hours of classroom and laboratory training (in §§ 35.55, 35.190, 35.290, and 35.390) for the alternate pathway only, will ensure safety and consistency of regulation on a national basis. Therefore, requirements for a minimum number of hours of classroom and laboratory training have been included in §§ 35.55(b)(1)(i), 35.190(c)(1), 35.290(c)(1), and 35.390(b)(1) of the final rule. However, the added requirements, specifying a minimum number of hours of classroom and laboratory training, were not added to the requirements for recognition of specialty board certifications because the NRC believes that it is important to provide flexible options for boards to evaluate the adequacy of T&E related to radiation safety. This flexibility is provided by a combination of evaluation through examinations, and academic and practical T&E. The NRC believes that the requirements of certifying boards, including requirements for examinations, whose certification processes have

been recognized by the Commission or an Agreement State, will ensure the adequacy of radiation safety training. As part of their application for recognition of certifications, boards will be asked to provide information on how their examination process assesses the candidates' knowledge related to radiation safety as it pertains to the subject areas enumerated in the regulations. The NRC believes that specifying a minimum for the number of hours of classroom and laboratory training, in the alternate pathway, will help to ensure that training programs are of adequate length to properly cover the topics important to safe medical use of byproduct material, supplementing the T&E gained during supervised clinical training. Doing so will increase the rigor of the alternate pathway and provide useful and consistent standards for developing training programs. Specifying a minimum number of hours of classroom and laboratory training will also be useful to States in reviewing the adequacy of training programs and assist Agreement States in developing their T&E regulations to be consistent with the compatibility category B designation for T&E regulations.

The draft final rule, circulated to Agreement States for a 30-day comment period, ending on October 18, 2004, included requirements for a minimum number of hours of classroom and laboratory training (applicable to the alternate pathway only) as follows: § 35.55 – 200 hours, § 35.190 – 8 hours, § 35.290 – 80 hours, and § 35.390 – 200 hours. Twelve Agreement States provided comments on this issue, with nine of them being in favor of a minimum of 200 hours of classroom and laboratory training for § 35.390. Two Agreement States recommended minimums of 120 and 160 hours of classroom and laboratory training, respectively, for § 35.390. Eight Agreement States supported the proposed number of hours for §§ 35.55, 35.190 and 35.290, and two States suggested requirements ranging from 120 to 200 hours for these four sections. One commenter from an Agreement State stated that the risks associated with uses under § 35.200 is similar to those for uses under § 35.300 because the higher frequency of uses under § 35.200 results in more risk and that, therefore, the number of hours

of classroom and laboratory training should be the same (200 hours) in §§ 35.290 and 35.390. This commenter suggested that, for clarity, the term “classroom and laboratory training” be used in place of the term “didactic training” in sections where the latter term appears. The commenter also stated that the way the draft revisions to the regulations are now written, the preceptor statement seems to apply only to the alternate pathway, and that they should be restructured to ensure that information is provided in preceptor statements about hours of training and experience, including classroom and laboratory training. The commenter suggested restructuring the regulations and re-designating paragraphs so that paragraph “(d)” always included the requirements for preceptor statements.

During the ACMUI meeting on October 14, 2004, the ACMUI passed a motion recommending that the requirement for classroom and laboratory training, in § 35.390, be 80 rather than 200 hours. The ACMUI believes that the requirements for training in radiation safety and safe handling for medical uses under §§ 35.200 (no written directive required) and § 35.300 (written directive required), including the use of beta emitters, are similar. The total hours of training (classroom and laboratory, combined with work experience) is the same (700 hours) in §§ 35.290 and 35.390. Therefore, the ACMUI recommended that the number of hours required for classroom and laboratory training be the same as that required for § 35.290, i.e., 80 hours, because the knowledge required for radiation safety is similar for uses under both §§ 35.290 and 35.390. The ACMUI was also concerned that time taken for classroom and laboratory training required under § 35.390(b)(1)(i) would detract from time needed for training in other areas required of clinicians.

After consideration of both the ACMUI’s and Agreement States’ recommendations, the NRC staff analyzed the issue to determine the appropriate amount of classroom and laboratory training for approval of AUs under § 35.390. The NRC is adopting a requirement for 200 hours of classroom and laboratory training for the alternate pathway in § 35.390 because more

knowledge is necessary in the topic areas listed in § 35.390(b)(1)(i)(A) through (E), as enumerated below, to ensure the safe use of byproduct material for which a written directive is required.

1. Radiation physics and instrumentation – a wider variety of radionuclides, having a wider range of energies, both for beta and gamma emitters, is used. This affects understanding of how radiation interacts with matter, which impacts understanding of shielding as well as the effects of radiation, and choice and use of instrumentation to detect and measure radiation and to measure quantities of radionuclides.

2. Radiation protection – more knowledge of principles and practices of radiation protection is needed because of the wider variety of radionuclides and associated types and energies of radiations used under § 35.300. Because greater quantities of byproduct material are commonly used for therapeutic purposes, risks are greater for patients and patient care personnel as well as for the public after the release of patients. Evaluation of these risks and associated protective measures and practices necessitates more knowledge for uses under § 35.300 than for uses under § 35.200. More knowledge of principles and practices in radiation protection is needed because of a wider variety of modes of administration and physical forms of byproduct material, e.g., intravenous, intra-peritoneal, oral and liquids in catheters. Each of these factors necessitates different radiation safety considerations for patients, occupationally exposed personnel and members of the public. Radiation safety considerations relate both to the preparation and use of byproduct material for medical purposes, and may extend to the treatment of patients in the operating room and to the pathology staff.

3. Mathematics pertaining to the use and measurement of radioactivity – Mathematics related to dosimetry is more complex for the wider variety of radionuclides, greater quantities, different types of radiation, and the broader purposes of use. Whereas byproduct material is

used for diagnostic purposes under § 35.290, uses under § 35.390 are common for various therapeutic purposes.

4. Chemistry of byproduct material for medical use – a wide variety of chemical forms of byproduct material is used under § 35.300. These forms include ionic, bound-to-antibodies, and simpler chemical species, resulting in differences in uptake in the body and various organs and tissues (biodistribution), and elimination. Agents are used both for diagnostic and therapeutic purposes.

5. Radiation biology – more knowledge of radiation biology is needed because byproduct material are administered in greater quantities, both for diagnostic and therapeutic purposes, resulting in the potential for a greater variety of radiation effects and greater potential for harm. Risk assessments sometimes involve consideration of immediate biological effects whereas this is not usually a consideration in diagnostic applications under § 35.200.

In addition to these considerations, the NRC notes that new medical applications of byproduct material are evolving under § 35.300. Examples include more common use of byproduct material for alleviation of bone pain and for treatment of metastatic disease. This results in a need for additional knowledge of a wider variety of applications of physical and chemical forms of byproduct material.

The NRC determined that the minimum amount of classroom and laboratory training should be 200 hours by reviewing the content of training courses that an individual might attend to satisfy the requirements in § 35.390(b)(1)(i). This training involved 200 hours of classroom and laboratory training.

The requirement for 200 hours of classroom and laboratory training is also incorporated into the final rule for individuals to qualify as ANPs because nuclear pharmacists may be involved in the preparation of dosages of byproduct material for uses under § 35.300 as well as under §§ 35.100, 35.200 and other uses specified in 10 CFR Part 35. Therefore, these

individuals will be involved in high-risk activities related to use of byproduct material, including wet chemistry. Their work may also involve greater quantities of byproduct material because they may dispense dosages from stock-quantities. Greater quantities are also used for short half-life radionuclides which decay between preparation and administration to patients.

The minimum number of hours of classroom and laboratory training for uses under § 35.200 is 80 hours because the complexity and level of knowledge required is less than for uses under § 35.300. The NRC believes that the frequency of use of byproduct material should not be considered in evaluating the risk to individuals from uses of byproduct material under § 35.200, for the purpose of determining the requirement for hours of classroom and laboratory training to be required for such uses. Rather, the NRC believes that other factors should be considered in this regard, e.g., adequacy of size and scope of a radiation safety program to ensure safe uses of byproduct material. However, because procedures such as elution of radionuclide generators and preparation of drugs labeled with byproduct material are conducted under § 35.200, the minimum was set at a greater level than for uses under § 35.100, for which risks are significantly less and for which the minimum requirement was set at 8 hours of classroom and laboratory training, in § 35.190.

The NRC recognizes that the minimum number of hours of classroom and laboratory training for uses of licensed byproduct material specified in these sections differs to some extent from the minimum number of hours of classroom and laboratory training specified for similar uses of such material in Subpart J. However, in determining the minimum number of hours of classroom and laboratory training to be required for each use, the NRC also recognized that the uses specified in sections of Subpart J are different from those covered in Subparts D through H and that the medical use of byproduct material has evolved and changes have taken place in the available technology for use in each of these areas since the promulgation of Subpart J. The NRC has considered these factors in determining the minimum

number of hours of classroom and laboratory training to be required for uses in Subparts B and D through H.

The NRC also agrees with the comment that the term “classroom and laboratory training” should be used in place of the term “didactic training.” The regulations in §§ 35.50(b)(1)(i) and 35.55(b)(1)(i) have been revised to use the term “classroom and laboratory” in place of “didactic training.”

The NRC has revised the language in the final rule so that the requirement for a preceptor attestation, for individuals to be approved as RSOs, AMPs, ANPs and AUs, now appears in §§35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390 (a), 35.392(a), 35.394(a), 35.396(a), 35.490(a), and 35.590(a). This approach helps make it clear that a preceptor statement is required for both the certification and alternate pathways. The NRC did not re-designate paragraphs to have the requirement for preceptor statements appear in paragraphs “(d)” in order to avoid extensive renumbering that would be necessary for other paragraphs.

Comment: One Agreement State commenter stated that there is too great of a reliance on a preceptor’s attestation/certification for physicians who qualify as AUs under the alternate pathway to provide adequate assurance that the individual will have obtained adequate radiation safety training. The criteria used by preceptors must be specifically and clearly defined and the qualifications for preceptors should be defined as well. Otherwise, AUs may give undue weight to the clinical aspects of training rather than to safety, and a clinically competent AU who has a poor radiation safety compliance history may provide a strong statement for an individual for whom radiation safety training was minimal.

Response: The criteria to be used by preceptors are stated in the regulations, including the qualifications required for an individual to serve as an AU. The NRC believes that competency of candidates to function independently as AUs is best assessed by AUs who have

experience performing the duties of an AU. The definition of "preceptor" appears in § 35.2. The qualifications for an individual to serve as a preceptor are specified in the requirements for preceptor statements in Subparts B and D through H. In general, they require that the preceptor be an individual who serves in the same capacity as the candidate for approval as RSO, AMP, ANP, or AU. The criteria for evaluation of T&E by preceptors are specified in each section of Subparts B and D through H. These criteria were chosen to ensure that they are risk-informed and performance-based and not unduly prescriptive in relation to the degree of risk associated with various types of use. Moreover, reflecting a performance-based approach, an AU is considered qualified to serve as a preceptor as long as his or her authorized status remains current. However, if an individual's status as an RSO, AMP, ANP, or AU, is revoked for non-compliance with the NRC's regulations, that person could no longer serve as a preceptor.

Issue 2: Should the word "attestation" be used in place of the word "certification" in preceptor statements? Should other changes to the wording or preceptor statements be made?

Comment: One commenter observed that "attest" and "certify" mean the same thing, and, because preceptors have been "attesting" for years, questioned changing terminology. Other commenters expressed support for making the change, with two commenters noting that the word "certification" should only be used in connection with the board process. Another commenter believes that the use of the word "attest" in place of "certify" would alleviate certain obstacles to individuals willing to serve as proctors.

Response: The NRC agrees that the use of the word "attest" and its various other forms (attestation, attesting) is more appropriate than the use of the word "certify" and would lead to more clarity in the regulations. Therefore, appropriate changes were made in the definition of

"preceptor" and in the requirements for preceptor attestations in the regulations. This change was also made, as a conforming change, in § 35.980(b)(2) of Subpart J to maintain consistency with other Subparts of 10 CFR Part 35.

Comment: The preceptor statement should be reworded to indicate that a preceptor "attest[s] to the candidate's knowledge and ability to handle radioisotopes in preserving the health and safety of the patient and the provider." The preceptor should not be required to attest to the general clinical competency of the candidate.

Response: The NRC agrees with the suggestion that the word "attest" should be used in place of "certify" in preceptor statements and has made these changes in the final rule. However, the other changes to the preceptor statements suggested by the commenter would result in the elimination of essential elements of a preceptor statement that the NRC continues to rely on to determine if an individual has satisfactorily completed requirements for T&E and has a level of competency sufficient to function independently as an RSO, AMP, ANP, or AU. The NRC clarified the meaning of the word "competency" in the section of the **Supplementary Information** entitled "Preceptor Attestation," by indicating that preceptors are not attesting to the general clinical competency of the candidate; this interpretation represents a restatement of the NRC's intent stated in the **Supplementary Information** for the current regulations, published on April 24, 2002 (67 FR 20249). Therefore, the other changes suggested by the commenter were not adopted in the final rule.

Comment: One Agreement State commenter believes that preceptors are not certifying "individuals," but they certify that the training received by an individual meets regulatory requirements. Otherwise, there may be an implication that organizations which provide training are relieved of any responsibility.

Response: The NRC agrees with the commenter's statement that preceptors do not "certify individuals." The purpose of preceptor attestations is stated in the regulations (e.g., in

the case of RSOs), to attest to the satisfactory completion of requirements for T&E to serve as an RSO and to an individual's having achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee.

Comment: An Agreement State commenter on the draft final rule stated that the definition for preceptor should confirm that the individual verifying training for another authorized user, medical physicist, nuclear pharmacist or RSO is also a licensed user/RSO on a specific medical license. The commenter indicated that it is also important for the preceptor to know that his or her own authorization on a medical license is at risk when signing a preceptor attestation.

Response: As stated above, the qualifications required for an individual to serve as preceptor are specified in the requirements for preceptor statements in Subparts B and D through H, and require that the preceptor be an individual who serves in the same capacity as the candidate for approval as RSO, AMP, ANP, or AU. Therefore, the NRC does not believe that the definition for preceptor should be revised. The NRC notes that a preceptor's authorization on a medical license is not, per se, "at risk" for signing a preceptor attestation. However, under Section 186 of the Atomic Energy Act, as well as the Commission's regulations in 10 CFR 30.10, a licensee, or applicant for a license, who deliberately submits to the NRC information that a person submitting the information knows to be inaccurate in some respect material to the NRC, may be subject to enforcement action. Under 18 USC §1001, any person who makes a willful false statement to the NRC may be subject to criminal sanctions.

Issue 3: Comments on other requirements related to preceptor statements.

Comment: Some commenters stated that the wording of the requirements for preceptor statements in the proposed rule implies that the preceptor has knowledge that an individual meets all of the requirements for board certification, including passing of a certification

examination, thereby establishing an unintended link between preceptor statements and examinations administered by boards. This may or may not be true, since, in some cases, a preceptor statement may be signed before the individual sitting for the board examination.

Response: The NRC agrees that preceptors should not be required to certify that individuals have completed all of the requirements that candidates for certification by a specialty board would be required to meet to obtain certification. The requirements for preceptor statements have been reworded in Subparts B and D through H of the final rule to remove requirements to attest to candidates having passed board administered examinations.

Comment: While agreeing that the change from certification to attest should be made, other commenters recommended that the following be inserted in place of the first sentence of all preceptor paragraphs in the December 9, 2003, draft: "Has obtained written attestation that the individual has satisfactorily completed the required training in paragraph (a)(1) or (b)(1) of this section and has achieved a level of knowledge and demonstrated the ability to safely handle radioisotopes to ensure adequate protection of public health and safety. The written attestation must be signed by a preceptor . . .."

One commenter indicated that the word "competency" should be dropped from the suggested preceptor statement because the phrase "has achieved a level of knowledge and demonstrated ability" is a demonstration of competency.

Response: As noted in the Discussion section of the **Supplementary Information**, the Commission directed the NRC staff, in SRM-02-0194 (dated February 12, 2003), that the preceptor statement remain as written in the current regulations (published April 24, 2002), and that the staff should clarify that the preceptor language does not require an attestation of general clinical competency but does require sufficient attestation to demonstrate that the candidate has the knowledge to fulfill the duties of the position for which certification is sought. Further, this form of attestation should be preserved both for the certification pathway and the

alternate pathway. Therefore, the suggestion related to the use of the word "competency" was not adopted in the final rule.

Comment: One Agreement State commenter stated that the proposed language regarding the requirement for obtaining preceptor statements is not the same in different sections. For example, § 35.290(a) reads, "meets the requirements in paragraph (c)(2) [has obtained a preceptor statement] and is certified." But § 35.390(a) reads, "is certified by a medical speciality board . . ." and "(c) has obtained written certification (from a preceptor)." While this accomplishes the same purpose, at first glance it appears that some boards do not require preceptor statements while others do. The language should be made more uniform for each discipline.

Response: The NRC agrees that parallel construction should be used in the language for requirements for preceptor statements for individuals who are board certified, and this approach was taken in the final rule. The requirement for a preceptor attestation for individuals to be approved as RSOs, AMPs, ANPs, and AUs now appears in §§ 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.396(a), 35.490(a), and 35.690(a). This approach also helps make it clear that a preceptor statement is required regardless of which training pathway is chosen.

Comment: One Agreement State commenter agreed that a preceptor statement should continue to be required for board certified individuals, stating that it is important for a person who knows a candidate to attest to the individual's competence in radiation safety.

Response: The NRC agrees with this comment. The NRC continues to rely on preceptor statements to determine if an individual has satisfactorily completed requirements for T&E and has a level of knowledge sufficient to serve as an RSO, AMP, ANP, or AU.

Comment: Several commenters expressed the opinion that the change in the requirements that de-couples requirements for a preceptor statement from requirements for

recognition of board certifications will result in a shift of burden for obtaining the statement from boards to individuals. One Agreement State commenter supported placing the responsibility for obtaining preceptor statements on individuals rather than on certification boards as a prerequisite to the certification process. Other commenters recommended that the NRC retain the preceptor letter requirement as a prerequisite to recognition of board certifications. They questioned what is gained by dropping requirements for preceptor statements from requirements for recognition of board certifications. An Agreement State commenter opposed separating requirements for preceptor statements from requirements for recognizing board certifications on the grounds that it integrates less uniformity and reliability into the training process. According to the commenter, a large number of physicians are currently denied authorizations because of inadequate preceptor statements, and this will only increase if these statements are not reviewed and issued by a valid source such as approved certification boards, thereby increasing the shortage of approved AUs.

Response: The NRC believes that individuals will continue to be involved in the process of documenting T&E and that the shift in responsibility is primarily from the involvement of boards in the process to licensees, which will be subject to the new requirement for submitting the preceptor statement to the NRC under § 35.14(a). The NRC removed the requirement for boards to obtain preceptor attestations, as a condition of recognition of board certifications, upon the recommendation of the ACMUI, which indicated that the requirement should be de-coupled from requirements for recognition of board certifications because individuals may obtain the preceptor statement required by the NRC after they have obtained their board certifications. This approach will enable a more flexible approach to satisfying the requirement for preceptor statements. The NRC believes removal of the requirement for a preceptor statement from requirements for recognition of specialty board certifications will not result in less uniformity in the process of training or decrease the number of individuals who are

approved as AUs because the responsibility for obtaining preceptor statements will still rest with individual candidates for approval as AUs, and the statements now must be submitted to the NRC or an Agreement State, rather than to a certification board. The NRC also notes that the final rule does not prevent specialty boards from requiring preceptor statements.

Comment: One commenter stated that the NRC should not require written preceptor certifications for the certification pathway because certification boards already require letters of endorsement to verify candidates' work experience and qualifications, and candidates must also pass a multi-part examination to assess knowledge and fitness to practice in a particular medical specialty. Therefore, it is redundant for the NRC to require preceptor statements. Furthermore, preceptors who are not involved in a specialty board's certification practice can only verify that an individual possesses a valid certificate. In addition, the commenter questions the justification for this new requirement.

Some commenters stated that the requirement for preceptor statements should be eliminated for board certified AUs, AMPs, and ANPs; they should only be required for those requesting authorization via the alternate pathway and for RSOs. Board certification and continued experience are satisfactory demonstration for meeting the radiation safety requirements to perform those authorized activities as AU, AMP, or ANP. The commenters believe that there is no evidence to support that any added benefit would be provided by requiring a preceptor statement for these individuals. Removing requirements for obtaining preceptor statements would also minimize the delay in approval of these individuals by the appropriate regulatory agency or the Radiation Safety Committee.

Response: The NRC continues to rely on preceptor statements to determine if an individual has satisfactorily completed requirements for T&E and has a level of knowledge sufficient to serve as an RSO, AMP, ANP, or AU. The NRC believes that it is essential to have individuals who are familiar with the duties of RSOs, AMPs, ANPs, and AUs, through personal

experience, to serve as preceptors. Individuals who serve in these positions are best qualified to attest that an individual has achieved a level of competency sufficient to function independently as an AMP, ANP, AU, or RSO. The concern expressed about the unavailability, or inability, of an authorized individual to complete a preceptor statement for an individual seeking authorized status was addressed in the final rule by modifying the definition of a preceptor, in § 35.2, to permit verification by the preceptor of required training and/or experience obtained previously or elsewhere. As indicated under the discussion of comments on the definition of "preceptor," the word "the" was removed from the phrase "the training and experience" in the definition of preceptor to help clarify that more than one individual may serve as a preceptor. The NRC does not agree that removing the requirement to obtain a preceptor statement would minimize the delay in approvals of individuals to serve as RSOs, AMPs, ANPs and AUs because other means would have to be used to evaluate the competency of these individuals, which would increase the amount of time needed for these approvals.

Comment: Some commenters stated that clarification that individuals may submit more than one preceptor statement, as applicable, for all categories of AU, AMP, or RSO, should be provided in the **Supplementary Information** for the final rule. Proposed §§ 35.490(c) and 35.690(c) indicate that the preceptor must be an AU of each type of medical unit for which the individual is requesting AU status. The language must be clarified to allow for different preceptors for multiple devices for which AU status is sought.

Response: The NRC recognizes that separate preceptor statements may be needed to document the T&E of individuals, e.g., in the case of an individual who receives training at different times in his or her career or in other circumstances when it may not be possible for only one preceptor to attest to some of the T&E that an individual has received. The NRC accepts multiple preceptor statements from licensees in these circumstances. As indicated under the discussion of comments on the definition of "preceptor" in Part III, the word "the" was

removed from the phrase “the training and experience” in the definition of preceptor to help clarify that more than one individual may serve as a preceptor.

Other Issues

Issue 4: Should the NRC continue to recognize the certifications of boards that have been recognized under the current regulations?

Comment: Two commenters believe that the CBNC (Certification Board of Nuclear Cardiology) should not be required to reapply for recognition of its certification because it was the only board that complied with the NRC requirements in 10 CFR Part 35 as promulgated on April 24, 2002 (67 FR 20249).

Response: The NRC believes that, because of the importance of board certification to establishing the adequacy of T&E for individuals to serve as RSO, AMPs, ANPs, and AUs, it is necessary to make a clear regulatory determination that all boards, both new and existing, meet the relevant regulatory criteria. Evaluation of board requirements against revised criteria in the final rule is necessary to make this determination. The NRC notes that, via a separate rulemaking, the expiration of Subpart J was extended for 1 year to October 24, 2005 (69 FR 55736, September 16, 2004); this will provide time for boards to apply for recognition under the revised regulation in the final rule. During this period, the NRC will continue to recognize the certifications of boards, including the CBNC’s, which are recognized under current regulations.

Issue 5: How will the NRC implement procedures for recognition of specialty board certifications? How will the NRC monitor trends in medical events to evaluate whether they are associated with a certification board’s requirements for certification?

Comment: In the **Supplementary Information** for the proposed rule, the NRC briefly discussed plans for implementation of changes to requirements for recognition of specialty board certifications. One commenter questioned these plans, asking how the NRC will monitor trends in medical events to see if they can be associated with inadequate training in radiation safety and if these trends can be related to a specialty board's requirements for training. The commenter agreed that the NRC should not conduct routine inspections of boards. The commenter indicated that the number of medical events reported by a certain board's diplomates is small, making it difficult to develop associations between trends and a board's requirements. The commenter also asked what statistical methods the NRC would use to make these determinations. One Agreement State commenter stated that the process by which a board would be delisted appears to be ineffective. For example, it is unclear how the NRC will track trends in diagnostic medical events and relate those trends to the adequacy of the radiation safety training component of a specific board certification, considering the fact that most diagnostic medical events are not reportable. The commenter stated that an analysis of current data should have been performed to determine if this approach would be effective.

Response: The NRC conducts a regulatory program to ensure safety. This regulatory program is also important to the identification of issues related to T&E that may, in turn, point to issues associated with the certification process of a specialty board. The NRC also requires that medical events be reported to the NRC and Agreement States. Bi-monthly reviews of events in the Nuclear Materials Events Database (NMED) provide a means for identifying trends in medical events in Agreements States and among NRC licensees that may lead to follow-up and review of adequacy of specialty board certification requirements. The NRC reviewed recent data and determined that radiation safety training related to board certification programs is adequate. The NRC staff has initiated consultations with the ACMUI to review medical events to determine if action is needed when problems arise including trends in medical

events reflected in NMED data. The NRC has a broad regulatory framework associated with medical T&E, involving review of specialty board certification processes, licensing and inspections of licensees, and medical event follow up and analysis. The NRC believes that these measures are sufficient to determine the adequacy of training related to a board's certification process.

Comment: One commenter believes that the NRC's plan to review a specialty board's certification program is particularly troubling. The NRC should not expect a certification board to jeopardize the security of its examination by allowing the NRC to review the examination and should not influence the content of a board's examination. The commenter believes that, because of the NRC's lack of expertise concerning the practice of medicine, the NRC is not in a position to determine the content of an examination. Rather, only a specialty board can make this judgement.

Response: The NRC will only review board examinations if it determines that a series of medical events is associated with a particular type of use and if the trend can be attributed to inadequate training in radiation safety. In addition, the NRC has methods to protect proprietary information in examinations; 10 CFR 2.390, "Public inspections, exemptions, requests for withholding," provides procedures for protection and nondisclosure of information that contains trade secrets, commercial or financial information obtained from a person, and privileged or confidential information. The NRC will consult with the ACMUI to seek advice, as necessary. Further, if safety problems are found that relate to the requirements of specialty boards for certifications, the NRC will work with boards to resolve these problems, including inadequacies in examinations if that is identified as a source of the problem.

Comment: One commenter stated that, while it is acceptable that the NRC does not plan to implement the rule by inspecting boards, the entire program for recognition of board certifications is in question unless the NRC reviews copies of training programs used by the

boards and has some kind of regulatory basis to implement enforcement of these commitments, if necessary.

Response: While the NRC does not plan to inspect training programs, it believes that specialty boards have a strong incentive to ensure that their certification procedures will ensure the safe use of byproduct material in medicine to protect the integrity of their certifications as well as to gain recognition from the NRC or an Agreement State. The NRC also believes that if a board's certification requirements are deficient, the possibility of delisting and loss of recognition is also a strong incentive for a specialty board to correct deficiencies. Further, as stated in the **Supplementary Information** for the current regulations, the NRC will investigate any allegations regarding inadequate training programs on a case-by-case basis.

Comment: One Agreement State commenter stated that, while it appears that posting approved boards on the NRC web site is appropriate, it is not clear that Agreement States will have input into the review/approval process.

Response: The NRC's current regulations for recognition of specialty board certification processes provide for recognition by either the NRC or Agreement States but do not require consultation between States or between States and the NRC. The regulations provide clear criteria for recognition of board certification processes.

Issue 6: How will revised requirements for T&E affect individuals who are now in training?

Comment: One commenter stated that there has been no requirement for fellows or residents currently in training to document T&E on a case-by-case basis. Therefore, physicians would be adversely affected by this new requirement, which would require a retrospective analysis of data that may not have been kept. Accordingly, the proposed T&E requirements

must be applicable only to those who begin training after the date of implementation of the final rule.

Response: The NRC believes that the revisions to requirements for T&E of AUs do not result in such extensive changes from current requirements that it should create difficulty for individuals to document their T&E. The ACMUI noted in its recommendations to the NRC for the development of the proposed rule (see SECY-02-0194) that it expected that the requirements of all boards for certification, and currently recognized, would satisfy revised requirements. Thus, there should be little change in what an individual would be expected to present to a board to gain certification. Further, the changes to the requirements for the alternate pathway are relatively few. Thus, these changes will not make the task of documenting T&E significantly more difficult. The NRC believes that these requirements are essential to ensuring adequacy of T&E for medical uses of byproduct material for which a WD is required and, therefore, that they should not apply only to individuals who begin training after the final rule is implemented. Further, under the provisions of § 35.57(b), experienced AUs (e.g., individuals identified on a license) are not required to comply with requirements for T&E in Subparts D through H of Part 35. Therefore, the suggestion offered by the commenter was not adopted.

Issue 7: Should the term “laboratory training” be defined?

Comment: One Agreement State Commenter expressed concern that the meaning of the term, “laboratory training,” should be more clearly defined. The commenter expressed concern that “laboratory” time could be interpreted as “clinical lab” which would be patient-care oriented rather than radiation-safety oriented.

Response: The NRC believes that defining the terms “classroom” and “laboratory” would not ensure compliance and would only serve to create a more prescriptive rule. However, the

NRC expects that clinical laboratory hours that will be credited toward meeting the requirements for classroom and laboratory training in Subparts B and D through H will involve training in radiation safety aspects of the medical use of byproduct material. The NRC recognizes, for example, that physicians in training may not dedicate all of their clinical laboratory time specifically to the subject areas covered in these subparts and will be attending to other clinical matters involving the medical use of the material under the supervision of an AU (e.g., reviewing case histories or interpreting scans). However, those hours spent on other duties, not related to radiation safety, should not be counted toward the minimum number of hours of required classroom and laboratory training in radiation safety. This type of supervised work experience, even though not specifically required by the NRC, may be counted toward the supervised work experience to obtain the required total hours of training (e.g., 700 hours for § 35.390). Similarly, the NRC recognizes that clinicians will not dedicate all of their time in training specifically to the subject areas described in Subparts D though H and will be attending to other clinical matters. The NRC will broadly interpret "classroom training" to include various types of instruction received by candidates for approval, including online training, as long as the subject matter relates to radiation safety and safe handling of byproduct material.

Part III – Comments on Specific Sections in the Proposed Rule

SUBPART A – General Information

Section 35.2 Definitions

Issue 1: Definitions of "authorized medical physicist" and "authorized nuclear pharmacist."

Comment: One Agreement State commenter stated that the current proposed definitions for “authorized medical physicist” and “authorized nuclear pharmacist” did not include individuals who had obtained preceptor statements and met the requirements for the alternate pathway, and that this did not appear to be correct.

Response: The NRC has considered this comment and determined not to change the definitions in § 35.2 for “authorized medical physicist” or “authorized nuclear pharmacist” to include individuals who are not board certified. These definitions clearly specify the individuals who are to be included within their scope and are not the same as the requirements for demonstrating the adequacy of training and experience. The means for a person to become an AMP, ANP, or AU, via the alternate pathway, are provided in Subparts B and D through H.

Authorized medical physicists are defined as individuals who are certified by specialty boards whose certifications are recognized by the NRC or an Agreement State or are identified as authorized individuals on a Commission or Agreement State license or permit. Authorized nuclear pharmacists are similarly defined and also include individuals who have been identified by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists, or are designated as authorized nuclear pharmacists in accordance with the requirements of § 32.72(b)(4). Although not noted by the commenter, the definitions similarly define an authorized user as a physician, dentist, or podiatrist who has been certified by a board whose certification has been recognized by the NRC or an Agreement State, or is identified as an authorized user on a Commission or Agreement State license or permit. These definitions are consistent with the requirements of § 35.13, which provide that a licensee must apply for and receive a license amendment before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license unless they are authorized individuals who either are certified by a board whose certification is recognized or are identified on a Commission or Agreement State license or by a commercial

pharmacy authorized to identify authorized nuclear pharmacists. Neither the language of these provisions nor the **Supplementary Information** accompanying the initial promulgation of, and modifications to, these sections indicate an intent to include within their scope individuals who are not board certified and who meet the training and experience requirements of the alternate pathway. In fact, there is a clear indication in the **Supplementary Information** of a specific intent that before allowing a physician who does not have board certification or is not listed on a license or permit to work as an authorized user, the specific licensee of limited scope must continue to submit a license amendment and obtain NRC approval (58 FR 33401; June 17, 1993).

As these definitions are not intended to parallel the training and experience requirements, the NRC has determined that changing the definitions as the commenter has suggested would be outside the scope of this rulemaking.

Issue 2: Definition of "stereotactic radiosurgery."

Comment: One commenter made a distinction between "stereotactic radiosurgery procedures," which the commenter indicated must be conducted in one session, and "stereotactic radiotherapy," which is conducted over extended periods of time with a linear accelerator. The commenter recommended amending the definition of "stereotactic radiosurgery" to include the words "in one session," and to add a new definition of "stereotactic radiotherapy" as "the use of external radiation in conjunction with a stereotactic guidance device to deliver partial therapeutic dose to a tissue volume over a series of sessions.

Response: The NRC believes that it is not necessary to qualify the definition of stereotactic radiosurgery as suggested by the commenter, or to add a new definition, because the more general term used, "stereotactic radiosurgery," is sufficient to include both types of treatments, and addition of the qualifiers could be unduly restrictive in the future.

Issue 3: Definition of “preceptor.” As currently defined, “preceptor” means 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.

Comment: One commenter suggested that the NRC revise the definition of “preceptor” to read “an individual who provides, directs, or has knowledge of training and experience required for an individual to become. . ..” Deleting the definite article “the” before “training” would clarify that more than one person may serve as a preceptor, and would clarify that the preceptor does not need to be the individual who trained the applicant. Addition of the phrase “or has knowledge of,” allows preceptors to address T&E that was not received under the supervision of the preceptor, e.g., training for new uses for which no AU exists, such as those that might be licensed under § 35.1000. Other commenters supported removal of the word “the” in the phrase, “the training and experience,” in the current definition. Another commenter also recommended rewording the definition of preceptor to include individuals who verify the training because, in some cases, the person who provides training, such as a vendor, may not meet the definition of a preceptor who provides or directs training and experience.

Response: The NRC agrees with the commenters and has removed the word “the” from the phrase “the training and experience” in the definition of preceptor. This change helps clarify that more than one individual may serve as a preceptor and that the regulations do not require the preceptor to be the same person who provides or directs training for an individual to be approved as an RSO, AMP, ANP, or AU. The NRC also agrees that there may be cases when the person who serves as preceptor may be able to verify that the training and experience meet requirements for T&E in the regulations (for example, training provided by a vendor for a specific type of use) and the definition of preceptor has been changed accordingly in the final rule.

Section 35.10 Implementation

Comment: One commenter stated that the current transition period, which ends on October 24, 2004, must be extended to allow time for boards to prepare applications and for processing of applications by the NRC, including review by the ACMUI.

Response: The NRC agrees that additional time for the changes to T&E should be allowed beyond October 24, 2004. Therefore, by way of a separate rulemaking, the NRC has amended 10 CFR Part 35 to extend the expiration of Subpart J for 1 year beyond the current expiration date to October 24, 2005 (69 FR 55736, September 16, 2004). This will allow time for specialty boards to prepare and submit applications for recognition under the revised regulations.

The final rule also contains amendments to requirements for T&E that relate to the alternate pathway and the submission of preceptor statements for board certified individuals under § 34.14(a). The NRC is providing, in § 35.10, for implementation of these requirements by October 24, 2005, to allow time for licensees and license reviewers to adopt revisions to requirements for T&E.

The NRC also notes that those board(s) whose certifications have been recognized by the NRC will continue to be listed on the NRC's web site until Subpart J expires on October 24, 2005; only those boards whose certifications are recognized under the provisions of this final rule will be listed after October 25, 2005.

Section 35.14 Notifications

Section 35.14(a) is being amended to require the submission of statements, signed by preceptors, in addition to a copy of a board's certification (required under current regulations). This change was made as a conforming change necessitated by amendments to requirements

in Subparts B and D through H of Part 35 which removed the requirement for specialty boards to obtain preceptor statements as a condition of recognition of their certifications and, instead, requires applicants for licenses to submit preceptor statements, effected by the amendment to § 35.14(a).

Comment: One Agreement State commenter noted that it is unfortunate that certification by an accepted board alone will no longer be adequate to become an AU, AMP, RSO, or ANP. Initially this could be confusing to licensees who will need to become accustomed to submitting copies of valid preceptor statements and board certificates with the notification required by § 35.14.

Response: The NRC removed the requirements for boards to obtain preceptor attestations, as a condition of recognition of board certifications, upon the recommendation of the ACMUI, which indicated that the requirement should be de-coupled from requirements for recognition of board certifications. The revised regulations require applicants to submit preceptor attestations along with copies of board certifications. The NRC believes that the regulations, as amended, clarify this change, and the NRC staff will work with applicants to resolve questions, should they arise.

Comment: One commenter stated that the requirements in § 35.14(a) should call for written attestation, not a written certification.

Response: The NRC agrees with the comment and made this change in the final rule. This change also brings the paragraph into conformance with changes made in requirements for preceptor statements in Subparts B and D through H of Part 35.

Subpart B – General Administrative Requirements

Section 35.50 Training for Radiation Safety Officer

Comment: One commenter suggested that the NRC should define "professional experience in health physics" and "at least 3 years in applied health physics" in § 35.50(a)(2), expressing concern that, if full-time experience is required in the practice of health physics, then most radiologists would not qualify as RSOs.

Response: The NRC believes that these terms are in common usage and that it is not necessary to define the terms. The NRC believes that it is appropriate to require 1 year of full-time experience under the supervision of an RSO for candidates to meet requirements for T&E, via the alternate pathway, to ensure that they are able to serve independently as RSOs. Therefore, the NRC has retained the requirement for 1 year of full-time, supervised experience, with the exception of the new provisions in § 35.50 for approval of medical physicists as RSOs, for which a requirement for 2 years of full-time experience is required.

Comment: After stating support for proposed changes to § 35.50 that would permit medical physicists who are not AMPs to serve as RSOs, some commenters also indicated that the phrase referring to certification by a board whose certification process has been recognized "under § 35.51 (a)" should be deleted from § 35.50(d)(2)(i). These commenters believe that including the connection would limit RSO medical physicists to medical physicists practicing in therapy. These commenters believe that it is critical that qualified medical physicists other than AMPs be able to serve as an RSO. Medical physicists, who are certified in diagnostic radiology or nuclear medicine, need to continue to be able to serve as an RSO.

Response: The NRC agrees that certain medical physicists may be well qualified to serve as RSOs. AMPs may now serve as RSOs. Therefore, § 35.50 has been amended to provide additional criteria for a medical physicist to qualify as an RSO. The new requirement for certification in medical physics by a specialty board that is recognized by the NRC or an Agreement State appears in § 35.50(c)(1), with requirements for recognition set out in § 35.50(a)(2). The criteria for NRC recognition of certification in medical physics for RSOs

does not include a requirement for examination in “clinical radiation therapy,” but provides a pathway for approval as RSOs of medical physicists certified in diagnostic radiology or nuclear medicine. The adequacy of T&E for individuals to serve as RSOs is ensured by requirements in the final rule for a preceptor statement and for training in radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. The NRC agrees with the commenters and believes that these requirements are appropriate to demonstrating the adequacy of T&E in radiation safety for individuals to serve as RSOs.

Section 35.51 Training for an authorized medical physicist

Issue 1: The requirements for T&E for AMPs include, in § 35.51(b)(1), that the training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy and brachytherapy services.

Comment: Two Agreement State commenters questioned the use of the term “high-energy” in the requirement for training of AMPs, suggesting that there is no definition for the term and that it might be interpreted differently by different States and individuals. The commenter asserted that, because experience with high-energy, external beam therapy is essential for approval of a medical physicist, it would seem appropriate that the term be understood.

Response: The term “high-energy” is used in the rule text in §§ 35.51(a)(2)(ii) and 35.51(b)(1) to specify the type of training to be included in T&E for AMPs. The NRC revised §§ 35.51(a)(2)(ii) and 35.51(b)(1) to indicate that high-energy radiation is considered to be photons and electrons with energies greater than or equal to 1 million electron volts, which is consistent with the definition of high-energy used by the International Commission on Radiation

Units and Measurements in Report 42, Use of Computers in External Beam Radiotherapy Procedures with High-Energy Photons and Electrons.

Issue 2: During the transition from previous regulations and changes under the final rule on T&E, should medical physicists, serving in functional roles as AMPs but not named on licenses, be allowed to continue serving as AMPs?

Comment: The ACMUI suggested that the rule grandfather those medical physicists, who serve as authorized medical physicists for intravascular brachytherapy, high-dose rate brachytherapy, cobalt-60 teletherapy, and cobalt-60 gamma knife therapy, to allow them to serve as AMPs in these respective categories regardless of whether they are currently listed on Agreement State or NRC licenses. Other commenters agreed, expressing concern that some Agreement States have not established processes for credentialing physicists authorized to perform critical QA and safety checks for intravascular brachytherapy, or gamma stereotactic treatments, and that some Agreement States, which have established requirements for T&E for these AMPs, do not explicitly list them on licenses. Therefore, this issue should be clarified so there could be an initial pool of AMPs to serve as preceptors and any physicist who meets the requirements of the board certification or alternate pathway under § 35.51, and has clinical experience performing AMP duties in the past 7 years, should be grandfathered.

Response: Prior to the implementation of current regulations in Part 35 (published on April 24, 2002; 67 FR 20249), the NRC staff evaluated, on a case-by-case basis, the qualifications of individuals to perform the functions of medical physicists and identified them as AMPs on NRC licenses. These individuals are “grandfathered” under §35.57(a). Hence, the concern of the ACMUI would relate primarily to those medical physicists performing functions for licensees of Agreement States but who are not identified on Agreement State licenses. To “grandfather” (approve as AMPs) these medical physicists in Agreement State, it is necessary

to evaluate the training and experience of these individuals to serve as AMPs to ensure that they have achieved a level of radiation safety knowledge sufficient to function independently as an AMP for each type of medical unit for which the individual would be responsible. The NRC staff does not believe that it is appropriate to "grandfather" medical physicists to allow them to serve as AMPs, absent such an evaluation having been conducted. Regulatory agencies in Agreement States, that have not been identifying on licenses those individuals who have been authorized to serve as medical physicists for the types of use and of concern to the ACMUI should identify (approve) medical physicists on licenses and amendments for types of use for which status as an AMP is required under revised regulations, including previously authorized medical physicists. These individuals, who have been identified on a license, would also be able to serve as preceptors for individuals to become AMPs.

Issue 3: Requirements for clinical experience to serve as an AMP.

Comment: Some commenters believe that proposed § 35.51(a)(2)(i) would allow individuals with no clinical experience (e.g., research post-doctoral candidates supervised by a boarded physicist), to sit for board certification examinations. Therefore, they suggested the following change to § 35.51(a)(2): "Have 2 years of full-time practical training and/or experience in a clinical radiation oncology facility providing high-energy external beam therapy and brachytherapy services under the supervision of (i) a medical physicist who is certified by a board recognized by the Commission or an Agreement State, or (ii) physicians who meet the requirements for §§ 35.490 or 35.690 authorized users."

Response: As in the proposed rule, the regulations in the final rule for recognition of specialty board certifications for AMPs require candidates for certification to have 2 years of practical training and/or supervised experience in medical physics and to pass an examination which assesses knowledge and competence in clinical radiation therapy, radiation safety,

calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery. The NRC believes that these requirements, in combination with the requirements for type of use specific training and for a preceptor attestation that a candidate for AMP has achieved a level of competency sufficient to function independently as an AMP, are adequate to assess the T&E of candidates for status as AMPs.

Section 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist

Comment: The ACMUI suggested that licenses should be amended to provide that current authorized users of sodium iodine-131 for imaging and localization, involving greater than 30 microcuries, continue to be authorized for these uses.

Response: Section 35.57(b)(1) provides that AUs who are identified on a license or permit are not required to comply with the training requirements in Subparts D through H to continue performing those medical uses for which they were authorized before October 24, 2002 (the effective date of the current regulations). Under § 35.57(b)(2), the same provision applies to AUs authorized between October 24, 2002 and the effective date of this final rule, ([insert date 30 days after publication in the Federal Register]). NRC licenses are being amended accordingly.

Subpart D – Unsealed Byproduct Material - Written Directive Not Required

Section 35.290 Training for imaging and localization studies

Comment: The ACMUI suggested that the revised regulations should, in the future, allow § 35.200 practitioners to conduct any I-131 imaging and localization involving greater than 30 microcuries, excluding sodium iodine, without further training and experience.

Response: Section 35.57(b)(1) provides the exception sought by the commenter by not requiring AUs to comply with the training requirements in Subparts D through H and to continue performing those medical uses for which they were authorized before October 24, 2002 (the effective date of the current regulations). Section 35(b)(2) allows AUs, authorized between October 24, 2002 and the effective date of this final rule ([insert date 30 days after publication in the Federal Register]) to continue performing those medical uses for which they were authorized during this period. NRC licenses are being modified accordingly.

Comment: The ACMUI recommended that the NRC provide a clarification that, for the diagnostic use of I-131 as sodium iodide which falls under § 35.392 for diagnostic use only, the training which an individual may cite for uses under § 35.392 may also serve as credit as part of the 700 hours of training for uses under § 35.200.

Response: The NRC requirement for 80 hours of training for uses under § 35.392 may be credited towards the 700 hours of training for uses under § 35.200 under the current regulations in § 35.290 and under the final rule.

Subpart E – Unsealed Byproduct Material - Written Directive Required

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

Comment: A commenter indicated that the NRC is imposing a new requirement in its regulations for 700 hours of training for uses for which a WD is required. The commenter indicated that this is 620 hours more than is required for the use of sodium iodide I-131 in quantities up to 1.2 GBq (33 millicuries) for therapeutic applications, for which 80 hours of training is required under § 35.392. Further, an examination is required for recognition of certifications of specialty boards under § 35.390, but not under § 35.392. The commenter

stated that risk-based regulations could not be used to justify the requirement for 620 more hours of training given that only 80 hours of training are required for the use of I-131 for treatment, and that virtually all medical events related to the use of unsealed sources are due to the use of I-131. Another commenter expressed similar views and added that it is inconsistent to have minimal requirements for alternate training pathways while placing more prescriptive requirements for training on specialty boards that already require far more than the alternative pathway. The commenter stated that the NRC should reconsider the requirements for the alternate pathway to remove these inconsistencies.

Response: The NRC did not propose to change requirements for the number of hours of T&E for individuals to qualify as AUs via the alternate pathway under §§ 35.390, 35.392, or 35.394. The issues raised by the commenter were discussed extensively in the **Supplementary Information** for the current rule in response to public comments in Part II, General Issues, Section E, Training and Experience, published in the Federal Register on April 24, 2002 (67 FR 20249). That discussion indicates that the NRC agreed with comments indicating that the T&E requirements should be increased for individuals who wish to use byproduct material for which a WD is required. The number of hours required were increased from 80 to 700 hours in § 35.390 for uses of unsealed byproduct material for which a WD is required. In addition, the work experience in the administration of such dosages to patients must include at least three cases in each of the following categories for which the individual is requesting AU status: (1) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required; (2) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; (3) Parenteral administration of any beta-emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or (4) Parenteral administration of any other radionuclide, for which a written directive is required. Physicians

who are authorized under § 35.390 for all of these types of administrations also meet the requirements in §§ 35.190, 35.290, 35.392, and 35.394. The NRC continues to believe that the increase in T&E hours was needed because these physicians are authorized to elute generators and prepare radioactive drugs, as well as to administer a wide variety of radionuclides for which WDs are required. Thus, the associated radiation risks of the use could be greater. The discussion in the **Supplementary Information** for the current rule also indicates that requirements for T&E were carried forward into the current rule, in § 35.392, for AUs to perform oral administration of sodium iodide I-131 in dosages less than or equal to 1.22 gigabecquerels (GBq) (33 millicuries (mCi)), if they do not prepare radioactive drugs using generators and reagent kits. To qualify as an AU under this limited authorization, an individual must have 80 hours of classroom and laboratory training and supervised work experience that includes 3 cases involving the oral administration of sodium iodide I-131 in dosages less than or equal to 1.22 GBq (33 mCi). Finally, the discussion indicated that requirements were carried forward to the current rule, in § 35.394, for AUs to perform oral administration of sodium iodide I-131 in dosages greater than 1.22 GBq (33 mCi), and do not prepare radioactive drugs using generators and reagent kits. To qualify as an AU under this limited authorization, an individual must have 80 hours of classroom and laboratory training and work experience that includes 3 cases involving the oral administration of sodium iodide I-131 in quantities greater than 1.22 GBq (33 mCi). Physicians authorized under § 35.394 also meet the T&E criteria in § 35.392. Based on licensee use, NRC inspections, and experience with medical events reported since the current rule became effective, on October 24, 2002, the NRC continues to believe that the requirements in §§ 35.390, 35.392, and 35.394 are necessary and sufficient.

Comment: One commenter suggested that the NRC add “diagnostic radiology” to the description of residency programs, which now includes “residency training in radiation therapy or nuclear medicine training program or a program in a related medical specialty.”

Response: The NRC believes that the description of “residency programs” should be limited to those which have direct applicability to the use of byproduct material for which a WD is required. Use of the general term “related medical specialty,” allows for training in diagnostic radiology.

Comment: Some commenters believe that to recognize radiation therapy and nuclear medicine residency programs as they now exist, the T&E criteria in § 35.390(a)(1) should be changed to allow for a 2-year nuclear medicine residency program as an alternative to a 3-year residency program in radiation therapy.

Another commenter indicated that the requirement for a 3-year residency should be removed from § 35.390 because it is inappropriate for the NRC to specify training requirements related to the practice of medicine.

Response: The NRC agrees that the requirement for residency programs to be 3 years in duration should be removed from § 35.390. In the final rule, this section no longer refers to the duration of residency programs.

Comment: Two commenters requested that the requirements in § 35.390 be changed to permit individuals trained in radiation oncology residency programs to use unsealed sources under § 35.300. The totality of all work experience possessed by individuals who have completed an accredited residency program in radiation oncology should be considered. The rule should exempt these individuals from requirements in § 35.390(b)(1)(ii) because radiation oncologists have unique experience that qualifies them to perform therapeutic procedures using unsealed sources. Another commenter stated that the American Board of Medical Specialties (ABMS) certified nuclear medicine physicians, radiologists, and radiation oncologists have unique training, experience, and examinations that go well beyond the minimum requirements of the alternate pathway. Therefore, the NRC should only require in § 35.390 that any ABMS medical specialty board meet the same minimal requirements specified for the alternate

pathway in proposed § 35.390(b)(1)(ii). The commenter also suggested removal of any additional requirements for an ABMS board such as an examination, and approval of ABMS boards based upon their formal training and examination procedures which would be outlined by the boards in their applications for approval.

Response: The NRC agrees that physicians trained in radiation oncology may have adequate T&E for certain medical uses of unsealed byproduct material for which a WD is required. One pathway now exists (i.e., licensees may apply for approval of physicians to serve as AUs for use under § 35.300 via the alternate pathway), which includes a requirement for completion of a residency program that includes 700 hours of training and experience in basic radionuclide handling techniques, applicable to the medical use of unsealed byproduct material for which a WD is required, as specified in § 35.390(b)(1). The NRC understands, however, that there are classes of physicians who may be well qualified but do not meet the requirement for 700 hours of T&E for unsealed byproduct material. For example, physicians who meet the requirements for T&E for uses under §§ 35.490 or 35.690 have a good understanding of radiation which applies to the use of sealed sources that is common to the use of unsealed sources. However, the NRC believes that, because of the increased risk associated with the use of unsealed sources for which a WD is required, it is essential to ensure that AUs have adequate T&E for this use. Commenters suggested removing requirements for 700 hours of T&E for uses under § 35.300, but that would remove essential requirements for T&E for use of unsealed byproduct material for which a WD is required. Therefore, the NRC has included a new § 35.396 in the final rule to provide a pathway for becoming a AU for uses of byproduct material under § 35.300, for individuals who may have acquired adequate T&E other than that specified in § 35.390 and other sections of Subpart E. This new § 35.396, “Training for the parenteral administration of unsealed byproduct material for which a written directive is required,” specifies requirements for T&E that relate to the use of unsealed byproduct material

for which a WD is required. These requirements were modeled after the requirements in other sections of Subpart E and include 80 hours of T&E specific to the use of unsealed sources and experience with at least three cases involving parenteral administration of byproduct material for which a WD is required. Section 35.396 allows for individuals to take credit for T&E associated with other medical uses of byproduct material that may be applicable to the uses of unsealed byproduct material, e.g., individuals who are certified by boards who meet the requirements of §§ 35.490 or 35.690 for the use of sealed sources. The NRC believes that this new section will provide the flexibility needed to allow individuals, who do not meet other requirements in Subpart E, to serve as AUs for parenteral administration of byproduct material for which a WD is required while ensuring adequacy of T&E for these uses to be safe.

Comment: One commenter stated that § 35.390(b)(1)(ii)(G) deals with the therapeutic administration of certain unsealed sources orally and by parenteral administration, i.e., by way of the intestines. The commenter stated that, because radiopharmaceutical therapies are now delivered by a variety of routes, the term “parenteral administration” should be changed to “administration by any route.”

Response: The NRC believes that the hazards and precautions associated with parenteral administrations of unsealed byproduct material are significantly different from those associated with oral administrations and that the requirements in § 35.390(b)(1)(ii)(G) are sufficiently broad as to cover the various uses for which a WD is required. Therefore, the NRC has retained requirements for experience with both oral and parenteral administrations for which a WD is required. The NRC also notes that the medical use of byproduct material under § 35.300 is not limited to “therapeutic” administrations, but applies to uses for which a WD is required (see § 35.40 for related requirements).

Comment: The ACMUI recommended removing the requirement for work experience with elution of generators and measuring, testing, and processing of eluates for preparation of

radiolabeled drugs in § 35.390(b)(1)(ii)(F). The ACMUI believes that it is not necessary to require all users of byproduct material, under § 35.300, to have experience with elution of generators and, further, that it is sufficient to require, in § 35.390(b)(1)(ii)(C), work experience with safely preparing patient or human research dosages. However, the ACMUI recommended that the requirement for elution of generators be retained for training in the use of byproduct material for individuals who may become AUs under provisions of § 35.290(b) by virtue of having been approved as an AU under § 35.390. A conforming change was recommended for § 35.100(b) for those AUs who qualify to prepare dosages if they meet the requirements in § 35.390, and in [revised] § 35.290(c)(2) for requirements for preceptors who meet the requirements of § 35.390.

Response: The NRC agrees with the recommendation of the ACMUI to remove the requirement for elution of generators and eluates in § 35.390(b)(1)(ii)(F) because this should not be required for AUs who do not need to use generators for uses of byproduct material under § 35.300 and because there is a requirement for safely preparing dosages in § 35.390(b)(1)(ii)(C). This change was made in the final rule along with conforming changes to retain the requirement for this experience in §§ 35.100(b), 35.200(b) and 35.290(b).

Comment: One commenter stated that the Accreditation Council for Graduate Medical Education (ACGME) was incorrectly referred to as the “Accreditation Council on Medical Education.”

Response: References to the ACGME have been corrected in the discussion of changes to §§ 35.390, 35.490, and 35.690.

Section 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)

Comment: One commenter suggested that there should be a grandfathering clause in § 35.392 to allow AUs who were permitted to perform diagnostic total body imaging scans, previously under § 35.200, when the scans were classified as “diagnostic” and “therapeutic” rather than as procedures for which WD is required, to continue to perform these procedures.

Response: Section 35.57(a) provides that experienced AUs, identified on a license or permit, are not required to comply with the training requirements in Subparts D through H to continue performing those medical uses for which they were authorized before October 24, 2002 (the effective date of the current regulations). This provides the “grandfathering” requested by the commenter.

Subpart H of Part 35 – Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

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

Comment: One commenter stated that AUs should be required to be neurosurgeons for use of gamma stereotactic radiosurgery treatments because a neurosurgeon is the only trained physician who has the knowledge unique to understanding the neuroanatomy of the brain. The commenter also suggested other changes to regulations, including a recommendation that the NRC require that WDs for gamma stereotactic radiosurgery be signed by both a treating neurosurgeon and radiation oncologist and that a neurosurgeon should be required to be physically present during treatments involving the gamma unit, with the radiation oncologist also present during the initiation of treatment.

Response: The NRC believes that it would be an unwarranted intrusion into the practice of medicine to specify that only neurosurgeons may serve as AUs for the use of byproduct

material in stereotactic radiosurgery. The NRC believes that sufficient protections are included in Subpart H of Part 35 and other applicable sections of 10 CFR Part 35 to ensure that licensees develop safety procedures and training to ensure safety. They include several requirements for safe use of byproduct material specific to high dose rate units in § 35.615(a)-(g) as well as requirements for the physical presence of an authorized user and authorized medical physicist (in § 35.615(f)(3)).

Part IV – Implementation by Agreement States – Timing and Compatibility

Issue 1: Should Agreement States establish the requirements to conform with this proposed rule by October 24, 2005, or should they follow the normal process and be given a full 3 years to develop a compatible rule?

Comment: Agreement State commenters were generally in agreement that they should have 3 years to adopt the final rule. One commenter stated that there is not a basis for considering emergency action, and that time is needed to allow for States to develop implementation procedures as well as revising their regulations. Another commenter noted that a requirement to adopt the final rule by October 25, 2005, would result in that State not meeting Compatibility B requirements.

Other commenters indicated that it may take a full 3 years for some Agreement States to adopt comparable regulations, but they should be urged to do so as soon as practical, and the compatibility level for these regulations should remain as compatibility B. One commenter states that Agreement States can and should meet the October 24, 2005, deadline for developing a compatible rule. The commenter believes there is much confusion and misunderstanding on the part of applicants seeking AU status as they have one [or more] sets of requirements in Agreement States and another in non-Agreement States. In some States,

these changes will require legislative action and the process needs to be started immediately to achieve compliance with the NRC's requirements. The commenter opposed this delay in the final implementation, indicating that extension of the deadline is quite unreasonable and unnecessary.

Response: The NRC acknowledges that the adoption of the final rule may take legislative action in some Agreement States and that some legislative cycles are up to 2 years in length. To allow adequate time for all Agreement States to adopt the final rule, and help avoid transboundary issues relating to differing standards between States, the NRC has determined that 3 years will be allowed for adoption of this Compatibility B final rule.

Comment: One commenter stated that obstacles to obtaining licensure in individual States discourage endocrinologists from providing treatment with I-131 when, in fact, endocrinologists, with their broad base of experience and training in all forms of thyroid disease and access to various forms of thyroid testing, are in the best position to judge the timing and appropriateness of radioiodine treatment.

Response: Current regulations, in §§ 35.392 and 35.394, include requirements that are specifically intended to enable endocrinologists (and other physicians) to obtain authorized user status for oral administration of sodium iodide I-131 for which a written directive is required. The requirements include 80 hours of classroom and laboratory training in subjects applicable to this usage plus work experience covering procedures important to this usage, including administering dosages to at least 3 patients or human research subjects. Preceptor statements required in the regulations can be completed by users authorized under these sections. The revised rule maintains these provisions. Because requirements for T&E are designated as compatibility category B, Agreement States must establish requirements that are essentially identical to NRC's.

Comment: One commenter suggested that the NRC enforce the compatibility requirements for Agreement States to comply with the requirements for T&E, published in the revised 10 CFR Part 35 on April 24, 2002, by October 25, 2005. The issues in the proposed rule are limited and do not affect the core of the training and experience requirements. The commenter indicated that progress on implementing compatibility in the Agreement States has been very slow. In some States, the regulatory changes must be implemented by legislative action, and the process should be started immediately to achieve compliance with the Federal mandate. Further delay in the adoption of the T&E requirements will inject added uncertainty into the process and delay unnecessarily the final resolution of the T&E issue.

Response: The NRC disagrees with the commenter's assertion that the amendments proposed do not affect 'core' requirements for T&E. Changes between current regulations and the final rule are substantial and Agreement States will need time to adopt the regulations, as noted in the commenter's observation that, in some States, legislative action will be required to adopt revised requirements for T&E. Therefore the NRC is allowing the full three years for adoption of the final rule.

Issue 2: Additional issues relating to implementation by Agreement States: Consistency of requirements

Comment: Three commenters indicated that the regulations on T&E should remain classified as Compatibility B.

Response: The NRC has not changed its compatibility designation for requirements for T&E in the final rule; they remain classified as Compatibility B.

Comment: Some Agreement State commenters stated that T&E requirements are designated as Compatibility B because of transboundary issues. However, consistency will not be ensured unless a minimum number of classroom hours are specified for AUs in §§ 35.190,

35.290, and 35.390, and for nuclear pharmacists in § 35.55. Each Agreement State will either accept whatever is submitted by an applicant or will designate a minimum number of hours that will be accepted. In either situation, inconsistency will exist.

Response: The NRC's designation of requirements for T&E as Compatibility B is intended to establish uniformity regarding requirements to ensure consistency of requirements for T&E between Agreement States and between the NRC and Agreement States. The NRC agrees with the assertion of the Agreement States that a specification for a minimum number of hours of classroom and laboratory training will promote consistency of regulations between Agreement States, and between the NRC and Agreement States when applied to the alternate pathway. However, this requirement need not be added to requirements for recognition of specialty board certifications to ensure consistency. For these reasons and those discussed in Part II, Issue 1, of the Summary of Public Comments, requirements for a minimum number of hours of classroom and laboratory training have been included in §§ 35.55(b)(1)(i), 35.190(c)(1), 35.290(c)(1), and 35.390(b)(1) of the final rule. These amendments to the regulations will also help ensure that Agreement States maintain Compatibility B status of their regulations for T&E.

Comment: A commenter for OAS indicated that, in response to a poll, some Agreement State commenters argued against categorizing requirements for T&E as Compatibility B. Comments included the argument that this has diminished safety for certain uses of byproduct material, e.g., for oral administrations of I-131 under §§ 35.392 and 35.394. One commenter also noted that a national standard for T&E makes sense because some States use the T&E evaluation of other licensing jurisdictions as part or all of their review of qualifications of applicants to become AUs. One commenter noted, however, that some Agreement States have, in the past, disagreed with the NRC's requirements for T&E and have effectively licensed

users with differing qualifications, and recommended a change of designation for T&E regulations to Compatibility C.

Response: The issue of adequacy of T&E for oral administration of I-131 sodium iodide was thoroughly reviewed by the NRC in the **Supplementary Information** when the current regulations for medical use of byproduct material were developed for the revision of 10 CFR Part 35, published on April 24, 2002 (67 FR 20249). This analysis included a careful consideration to numerous public comments in relation to adequacy of T&E. Many of the issues raised by the commenters to justify a redesignation of T&E requirements as Compatibility C were also given considerable review during the development of the current regulations and the conclusion was reached that the assignment of the specific compatibility categories to the requirements in the current regulations was necessary to assure that byproduct material is used with a uniform level of radiation safety nationwide. Therefore, a basis for redesignation of Compatibility is unnecessary. Further discussion of the Compatibility designation for requirements for T&E appears above.

V. Summary of Final Revisions.

Section 35.2 - Definitions.

The definition of “preceptor” is changed from “Preceptor means an individual who provides or directs the training and experience . . ..” to read “Preceptor means an individual who provides, directs, or verifies training and experience . . ..” The definition of “Radiation Safety Officer” is changed to include individuals who qualify as RSOs by meeting the new requirements in § 35.50(c)(1).

Section 35.8 Information collection requirements: OMB approval.

This section is amended to incorporate a conforming change related to the addition of § 35.396 to Subpart E of Part 35. The information collection related to this new section is noted in paragraph (b) by the addition of “§ 35.396" to the list of sections appearing therein.

Section 35.10 - Implementation.

This section is amended to incorporate a conforming change necessitated by the amendment of other sections. Paragraph (b) is amended to require implementation, by October 24, 2005, of §§ 35.50(a) and (e), 35.51(a) and (c), 35.55(a), 35.55(b)(1)(i), 35.190(a), 35.190(c)(1), 35.290(a), 35.290(c)(1), 35.390(a), 35.390(b)(1), 35.392(a), 35.394(a), 35.396(a), 35.396(c), 35.490(a), 35.590(a) and (c), and 35.690(a) and (c) and the requirement, in § 35.14(a), to provide a copy of written attestations to the Commission.

Section 35.13 - License amendments.

This section is amended to incorporate conforming changes necessitated by amendments of other sections. Paragraph (b)(3) is amended to reference requirements for training specific for types of use specified in new § 35.51(c).

Section 35.14 - Notifications.

This section is amended to add a requirement to paragraph (a) to submit a copy of a written attestation, signed by a preceptor, in addition to a copy of the board certification now required in this paragraph. The section is also amended to require licensees to provide verification of completion of relevant training for individuals permitted to work as authorized individuals under § 34.13(b)(4).

Section 35.50 - Training for Radiation Safety Officer.

This section is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board's certification to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway (§ 35.50(b) in the current regulations), paragraph (a) is amended to provide separate requirements for a specialty board's certification process. This includes a requirement to pass an examination, administered by diplomates of the specialty board, that evaluates knowledge and competency in areas that are important to functioning as an RSO. Requirements for training are changed to add requirements for a bachelor's or graduate degree from an accredited college or university in physical science, engineering, or biological science with a minimum of 20 college credits in physical science. Training requirements also include a minimum of 5 years of professional experience in health physics, including at least 3 years in applied health physics (graduate training could be substituted for up to 2 years of experience). Paragraph (a) is amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certifications. This requirement appears in paragraph (d) and applies to individuals for both the certification and alternate pathways. New paragraphs (a)(2) and (c)(1) are added that specify requirements for medical physicists to serve as RSOs. The term "classroom and laboratory training" is substituted for the word "didactic" in paragraph (b)(1)(i) to be consistent with usage in other sections. A new paragraph (e) is added to require training in radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks authorization. Paragraph (e) applies to all pathways. The requirement for a "written certification," signed by a preceptor, is changed to a requirement for a "written attestation," signed by a preceptor, in paragraph (d).

Section 35.51 - Training for an authorized medical physicist.

This section is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board's certification to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) is amended to provide separate requirements for a specialty board's certification process. This process includes a requirement to pass an examination, administered by diplomates of the specialty board, that evaluates knowledge and competency in areas that are important to functioning as a medical physicist. Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certifications and now applies to each individual seeking approval as an AMP via either the certification or alternate pathway and is added to paragraph (a). A new paragraph (c) is added to require training related to the type of use for which authorization is sought that includes "hands on" device operation, safety procedures, clinical use, and operation of a treatment planning system. Paragraph (c) applies to the certification and alternate pathways. In addition, for the alternate pathway (paragraph (b)(1)), the acceptable areas of concentration for degrees are expanded, and a requirement that the degree be from an accredited college or university is added. Paragraph (b)(1) is also amended to list the specific areas for which the individual needs to have training and work experience, instead of referring to other sections of 10 CFR Part 35, and allows for the T&E to be received in clinical radiation facilities that provide high-energy, external beam therapy with photons and electrons with energies greater than or equal to 1 million electron volts and brachytherapy services. The term "written certification" in paragraph (b)(2) is changed to "written attestation."

Section 35.55 - Training for an authorized nuclear pharmacist.

This section is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board's certification to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) is amended to provide separate requirements for a specialty board's certification process. This certification process includes a requirement to pass an examination, administered by diplomates of the specialty board, that evaluates knowledge and competency in areas that are important to functioning as an ANP. Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The requirement for didactic training in paragraph (b)(1)(i) is changed to specify that 200 hours of the 700 hours of training required under paragraph (b)(1) must be classroom and laboratory training; the term "classroom and laboratory training" is substituted for the word "didactic" to be consistent with usage in other sections. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certifications and now applies to each individual seeking approval as an AMP and is referenced in paragraph (a). The term "written certification" in paragraph (b)(2) is changed to "written attestation."

Section 35.57 - Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

This section is amended by adding two paragraphs, (a)(2) and (b)(2), to provide that (1) individuals identified as RSO's, AMPs or ANPs on a Commission or Agreement State license or permit, after the effective date (October 24, 2002) of the current requirements in Subpart B, and before the effective date of this final rule, may continue to serve in these positions; and (2)

physicians, dentists or podiatrists identified as AUs on a Commission or Agreement State license or permit, who perform only those medical uses for which they were authorized between October 24, 2002, and the effective date of this final rule, need not comply with the training requirements of Subparts D through H.

Section 35.75 - Release of individuals containing unsealed byproduct material or implants containing byproduct material.

Paragraph (a) is amended to remove “(draft)” from footnote 1.

Section 35.100 - Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

A conforming change is made in § 35.100(b)(2) to add, and thereby retain, a requirement, formerly incorporated by reference to § 35.390(b)(1)(ii)(F), for work experience with elution of generators and the measuring, testing, and preparation of labeled radioactive drugs for those individuals who qualify for preparation of dosages for use under § 35.100 as AUs approved under § 35.390. The addition is accomplished by adding a reference to § 35.290(c)(1)(ii)(G) in § 35.100(b).

Section 35.190 - Training for uptake, dilution, and excretion studies.

Paragraph (a) is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board’s certification to be recognized by the Commission or an Agreement State for uses under § 35.190. A requirement is added that candidates must pass an examination administered by diplomates of the specialty board. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certifications and now applies to each individual seeking approval

as an AU under § 35.100 and is referenced in paragraph (a). Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The introductory text of paragraph (c)(1) is amended to provide that a minimum of 8 hours of the 60 of training and experience, required in this paragraph, must be classroom and laboratory training. Paragraph (a)(1) is amended to clarify that this requirement does not apply to the certification pathway. The introductory text of paragraph (c)(1)(ii)(B) is amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments. The term "written certification" is changed to "written attestation" in paragraph (c)(2).

Section 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

A conforming change is made in §§ 35.200(b) to add, and thereby retain, a requirement, formerly incorporated by reference to § 35.390(b)(1)(ii)(F), for work experience with elution of generators and the measuring, testing, and preparation of labeled radioactive drugs, for those individuals who qualify for use under § 35.200 as AUs approved under § 35.390. The addition is accomplished by adding a reference to § 35.290(c)(1)(ii)(G) in § 35.200(b)(2).

Section 35.290 - Training for imaging and localization studies.

Paragraph (a) is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board's certification to be recognized by the Commission or an Agreement State for uses under § 35.290. A requirement is added that candidates must pass an examination administered by diplomates of the specialty board. The

requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certifications and now applies to each individual seeking approval as an AU under § 35.200. Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The introductory text of paragraph (c)(1) is amended to provide that a minimum of 80 hours of the 700 hours of training and experience, required in this paragraph, must be classroom and laboratory training. Paragraph (a)(1) is amended to clarify that this requirement does not apply to the certification pathway. Paragraph (c)(1)(ii)(B) is amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments. The term "written certification" is changed to "written attestation" in paragraph (c)(2). A conforming change is made in §§ 35.290(b) and 35.290(c)(1)(ii) to add a requirement for work experience with elution of generators and the measuring, testing, and preparation of labeled radioactive drugs for those individuals who qualify for use under § 35.290 as AUs approved under § 35.390. These requirements are also applicable to individuals serving as preceptors under § 35.290(c)(2).

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

This section is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board's certification process to be recognized by the Commission or an Agreement State for uses under § 35.390. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) is amended to provide separate requirements for a specialty board's certification process. The requirement for experience with administration of dosages in paragraph

(b)(1)(ii)(G) is no longer included in requirements for recognition of board certifications, but is retained as a requirement for individuals to become AUs for uses for which a WD is required by adding a reference, in paragraph (a), to paragraph (b)(1)(ii)(G). In paragraph (a)(1), the training and experience required for the certification pathway is changed to include a requirement that individuals complete residency training in a radiation therapy, nuclear medicine, or a related medical specialty training program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association. A requirement is added that candidates must pass an examination administered by diplomates of the specialty board. Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certifications and now applies to each individual seeking approval as an AU under § 35.390 and is referenced in paragraph (a). The introductory text of paragraph (b)(1) is amended to provide that a minimum of 200 hours of the 700 hours of training and experience, required in this paragraph, must be classroom and laboratory training. Paragraph (b)(1)(ii)(B) is amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments. Paragraphs (b)(1)(ii)(G)(1), (3) and (4) are amended to revise requirements for work experience involving parenteral administration of dosages, clarifying them to indicate that the experience is to be with cases for which written directives are required. Paragraph (a)(2) is amended to clarify that candidates must pass an examination that tests knowledge and competence in use of unsealed byproduct material for which a WD is required. Paragraph (b)(1)(ii)(F) is removed to eliminate the requirement for work experience with elution of generators and the measuring, testing, and

processing of eluates for preparing labeled radioactive drugs. The term “written certification” in paragraph (b)(2) is changed to “written attestation.”

Section 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).

Paragraph (a) is amended to include a statement that the names of recognized board certifications will be posted on the NRC’s web page. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certifications and now applies to each individual seeking approval as an AU under § 35.392 and is referenced in paragraph (a). Paragraph (c)(2)(ii) is amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments. The term “written certification” in paragraph (c)(3) is changed to “written attestation.”

Section 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).

Paragraph (a) is amended to include a statement that the names of recognized board certifications will be posted on the NRC’s web page. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certification processes and now applies to each individual seeking approval as an AU under § 35.392 and is referenced in paragraph (a). Paragraph (c)(2)(ii) is amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments. The term “written certification” in paragraph (c)(3) is changed to “written attestation.”

Section 35.396 - Training for the parenteral administration of unsealed byproduct material requiring a written directive.

A new § 35.396 is added to Subpart E. The section establishes T&E requirements applicable to AUs for the parenteral administration of unsealed byproduct material for which a written directive is required. The following individuals may serve as AUs under this section if they meet specified T&E requirements --

- Under paragraph (a), AUs under § 35.390 or, before October 24, 2005, § 35.930 for uses listed in §§ 35.390(b)(1)(ii)(G)(3) and 35.390(b)(1)(ii)(G)(4), or equivalent Agreement State requirements.
- Under paragraph (b), AUs for uses under §§ 35.400 or 35.600 or, before October 24, 2005, §§ 35.940 or 35.960, or equivalent Agreement State requirements.
- Under paragraph (c), physicians certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 35.400 or 35.600 or, before October 24, 2005, §§ 35.940 or 35.960.

The specified requirements for AUs under § 35.396 are as follows:

- T&E specific to the use specified in paragraphs (d)(1) and (d)(2), including 80 hours of classroom and laboratory training that includes topics and experience necessary for the safe use of unsealed byproduct material for parenteral administrations for which a written directive is required, and;
- Preceptor statements as specified in paragraph (d)(3).

Section 35.490 - Training for use of manual brachytherapy sources.

This section is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board's certification processes to be recognized by the Commission or an Agreement State. Instead of requiring that the

certification process include the same criteria as the alternate pathway, paragraph (a) provides separate requirements for a specialty board's certification process. In paragraph (a)(1), the training and experience required for the certification pathway is changed to include a requirement that individuals complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association. A requirement is added that candidates must pass an examination administered by diplomates of the specialty board. Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certification processes and now applies to each individual seeking approval as an AU under § 35.490 and is referenced in paragraph (a). The term "written certification" is changed to "written attestation" in the requirements for preceptor attestation in paragraph (b)(3). Paragraph (b)(2) is amended to include the Royal College of Physicians and Surgeons of Canada in the listing of organizations that can provide approval of the formal training program.

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

Paragraph (b)(3) is amended to change the term "written certification" to "written attestation."

Section 35.590 - Training for use of sealed sources for diagnosis.

Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. Paragraph (c) was added and applies to both the certification and the alternate pathways. This revision separates the

requirement for training in the use of the device for the uses requested from the requirement for 8 hours of classroom and laboratory training in basic radionuclide handling techniques.

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

This section is amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board's certification processes to be recognized by the Commission or an Agreement State for uses under § 35.600. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) is amended to provide separate requirements for a specialty board's certification process. Paragraph (a) is also amended to include a statement that the names of recognized board certifications will be posted on the NRC's web page. In paragraph (a)(1) the training and experience required for the certification pathway is changed to include a requirement that individuals complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association. A requirement is added, in paragraph (a)(2), that candidates must pass an examination administered by diplomates of the specialty board. The requirement for obtaining a preceptor statement is removed from the requirements for recognition of specialty board certifications and now applies to each individual seeking approval as an AU under § 35.690. Additionally, for the alternate pathway, paragraph (b)(2) is amended to include the Royal College of Physicians and Surgeons of Canada in the listing of organizations that can provide approval of the formal training program. The requirement for experience in "radiation oncology" in paragraph (b)(2) is changed to require experience in "radiation therapy." The term "written certification" is changed to "written

attestation" in the requirements for preceptor attestation in paragraph (b)(3). A new paragraph (c) is added to require training in device operation, safety procedures, and clinical use for the type(s) of use for which approval as an AU is sought. Paragraph (c) applies to all pathways.

Section 35.980 - Training for an authorized nuclear pharmacist.

Paragraph (b)(2) is amended to change the term "written certification" to "written attestation," a conforming change made to maintain consistency with other subparts of 10 CFR Part 35.

VI. Agreement State Compatibility.

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the Federal Register on September 3, 1997 (62 FR 46517), this final rule is a matter of compatibility between NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. The Compatibility classifications for sections amended in the final rule are unchanged. The new § 35.396 is classified as Compatibility Category B. A summary of compatibility classifications for amended sections in the final rule appears below.

Compatibility	Section
Compatibility Category B	§ 35.2, Definitions: preceptor, radiation safety officer; §§ 35.50, 35.51, 35.55, 35.57, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, 35.590, 35.690
Compatibility Category C	§§ 35.11, 35.75(a)
Compatibility Category H&S	§§ 35.100, 35.200
Compatibility Category D	§§ 35.8, 35.10, 35.13, 35.14, 35.980

A Compatibility Category B designation means the requirement has significant direct transboundary implications. Compatibility Category B designated Agreement State requirements should be essentially identical to those of NRC.

A Compatibility Category C designation means the essential objectives of this section should be adopted by the State to avoid conflicts duplications or gaps. The manner in which the essential objectives are addressed need not be the same as NRC, provided the essential objectives are met.

A Compatibility Category H&S designation means program elements are not required for purposes of compatibility; however, they do have particular health and safety significance. The

State should adopt the essential objectives of such program elements to maintain an adequate program.

A Compatibility Category D designation means that the essential objectives of the section are not required for purposes of compatibility and do not need to be adopted by the Agreement States.

VII. Implementation.

The revised regulations in 10 CFR Part 35 become effective on [insert date 30 days after publication in the Federal Register]. The Commission provides, by amendments to § 35.10(b), that licensees will have until October 24, 2005, to comply with the training requirements for authorized users, authorized medical physicists, authorized nuclear pharmacists, and Radiation Safety Officers. During this period, licensees will have the option of complying with either requirements of Subpart J, the expiration of which was extended by a separate rulemaking to October 24, 2005 (69 FR 55736, September 16, 2004), or the requirements in Subparts B and D through H of Part 35. The transition period will allow additional time for other specialty boards to seek NRC recognition of certifications as provided in §§ 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a). The transition period will also allow individuals from Agreement States time to satisfy the training requirements to work in NRC jurisdictions. The Commission also provides, by amendment to § 35.57, that individuals who have been named on existing Commission or Agreement State licenses and permits, between the October 24, 2002 (the effective date of current requirements for T&E, revised on April 24, 2002) and the effective date of this final rule, are exempt from the new requirements in Subparts D through H.

The effect of this change to the regulations is to “grandfather” those individuals named on an existing Commission or Agreement State license or permit, for those use(s) for which they have been approved to serve as an RSO, AMP, ANP, or AU.

VIII. Voluntary Consensus Standards.

The National Technology Transfer Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is modifying the training and experience requirements for radiation safety officers, authorized medical physicists, authorized nuclear pharmacists, or authorized users. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

IX. Finding of No Significant Environmental Impact: Environmental Assessment.

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required. The environmental assessment is presented below.

Introduction.

The NRC is amending its regulations governing the medical use of byproduct material to change its requirements for recognition of specialty boards whose certification may be used to

demonstrate the adequacy of the training and experience of individuals to serve as radiation safety officers (RSOs), authorized medical physicists (AMPs), authorized nuclear pharmacists (ANPs), or authorized users (AUs). The final rule also revises requirements for demonstrating the adequacy of training and experience for pathways other than the board certification pathway. This rulemaking is necessary to address the training and experience issue for recognition of specialty board certifications.

The Final Action.

This action amends the Commission's regulations governing the medical use of byproduct material (10 CFR Part 35). The final rule changes the requirements for recognition of specialty boards whose certification may be used to demonstrate the adequacy of the training and experience of individuals to serve as an RSO, AMP, ANP, or AU. This action also amends certain requirements for the training and experience of individuals who do not choose the board certification pathway.

During its revision of 10 CFR Part 35, the Commission became aware that, as a result of the changes to its training and experience requirements, specialty board certifications recognized by the NRC under the former regulations no longer would be qualified for recognition, and that this could result in a shortage of authorized individuals. As a temporary measure to address this issue, the Commission reinserted Subpart J to Part 35 into the final rule which was published in the Federal Register on April 24, 2002 (67 FR 20249). Subpart J to Part 35 was effective for a 2-year transition period, which would have expired on October 24, 2004. This action addresses the issue relating to recognition of board certifications after expiration of Subpart J on October 24, 2005.

Need for the Action.

This rulemaking is needed to address the training and experience issue for recognition of certifications of specialty boards by the NRC for approval of individuals to serve as RSOs, AMPs, ANPs, or AUs. Without this rulemaking, the issue of board recognition would not be addressed. Subpart J to Part 35 expires on October 24, 2005, and without this rulemaking, there could be a potential shortage of individuals authorized to perform medical procedures involving the use of byproduct material.

Alternatives to this Action.

An alternative to this final rule would be to take no action. Subpart J to Part 35 would expire on October 24, 2004. The no-action alternative is not favored because the issues related to training and experience, as they relate to NRC's recognition of specialty boards, would not be resolved, and this could result in a shortage of RSOs, AMPs, ANPs, and AUs.

Environmental Impacts of the Final Action.

The NRC prepared an environmental assessment as part of the development of the Part 35 final rule published in the Federal Register on April 24, 2002 (67 FR 20249). The conclusion from this environmental assessment was that the 10 CFR Part 35 amendments would have no significant impact on the public and the environment. Specifically, pertaining to the training and experience requirements, the environmental assessment stated: "The amendments to the training and experience requirements in 10 CFR Part 35 focus on knowledge and experience that is integral to radiation safety. These changes are expected to have no significant impact on public health and safety, occupational health and safety, and the environment." The NRC finds that the conclusion is still valid for the revisions to the training and experience requirements in this final rule. The revisions also focus on the knowledge and experience that is integral to radiation safety. The amendments to 10 CFR Part 35 are

expected to have no significant impact on the public health and safety, occupational health and safety, and the environment.

Agencies and Persons Consulted and Sources Used.

The environmental assessment for the final 10 CFR Part 35 rulemaking (67 FR 20249; April 24, 2002), was used in the preparation of this environmental assessment. The draft environmental assessment was sent to Agreement States and the Advisory Committee on the Medical Use of Isotopes for review and comment. The NRC staff has determined that this final action will not affect listed species or critical habitat. Therefore, no further consultation is required under Section 7 of the Endangered Species Act (16 U.S.C. Sections 1531 et seq). The NRC staff has determined that this action is not the type of activity that has potential to cause effects on historic properties. Therefore, no further consultation is required under Section 106 of the National Historic Preservation Act (16 U.S.C. Sections 470 et seq).

Finding of No Significant Impact.

Based on the foregoing environmental assessment, the NRC concludes that this rulemaking will not have a significant effect on the quality of the human environment. Therefore, the NRC has determined that an environmental impact statement is not necessary for this rulemaking.

The determination of this environmental assessment is that there will be no significant impact to the public from this action.

X. Paperwork Reduction Act Statement.

This final rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval numbers 3150-0010 and 3150-0120.

The burden to the public for these information collections is estimated to average 1.4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0010/3150-0120), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XI. Regulatory Analysis.

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The

analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. Single copies of the regulatory analysis are available from Roger W. Broseus, Office of Nuclear Material Safety and Safeguards, telephone (301) 415-7608, email RWB@nrc.gov.

XII. Regulatory Flexibility Certification.

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the NRC certifies that this rule will not have a significant economic impact on a substantial number of small entities. This final rule amends the regulations governing the medical use of byproduct material to change its requirements for recognition of specialty boards whose certification may be used to demonstrate the adequacy of the training and experience of individuals to serve as radiation safety officers, authorized medical physicists, authorized nuclear pharmacists, or authorized users. This rule also revises the requirements for demonstrating the adequacy of training and experience of individuals who do not choose pathways other than the board certification pathway. This rule will have no burden or economic impact on licensees because it does not add new requirements; it provides a revision to an existing option. Therefore, it does not fall within the scope of the definition of “small entities” set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 10 CFR Part 121.

XIII. Backfit Analysis.

The Commission has determined that a backfit analysis is not required for this final rule because these amendments do not include any provisions that would require backfits as defined in 10 CFR Chapter 1.

XIV. Small Business Regulatory Enforcement Fairness Act.

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR Part 35.

PART 35–MEDICAL USE OF BYPRODUCT MATERIAL

1. The authority citation for Part 35 continues to read as follows:

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); Sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

2. In § 35.2, the definition "radiation safety officer" is amended by republishing the introductory text and revising paragraph (1) of the definition, and the definition of "preceptor" is revised to read as follows:

§ 35.2 Definitions.

* * * * *

Preceptor means an individual who provides, directs, or verifies 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.

* * * * *

Radiation Safety Officer means an individual who–

(1) Meets the requirements in §§ 35.50(a) or (c)(1) and 35.59; or, before October 24, 2005, §§ 35.900(a) and 35.59; or

* * * * *

3. In § 35.8, paragraph (b) is revised to read as follows:

§ 35.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.396, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.900, 35.910, 35.920, 35.930, 35.940, 35.950, 35.960, 35.961, 35.980, 35.981, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047 and 35.3067.

* * * * *

4. In § 35.10, paragraph (b) is revised to read as follows:

§ 35.10 Implementation.

* * * * *

(b) A licensee shall implement the training requirements in §§ 35.50(a) and (e), 35.51(a) and (c), 35.55(a) and (b)(1)(i), 35.59, 35.190(a) and (c)(1), 35.290(a) and (c)(1), 35.390(a) and (b)(1), 35.392(a), 35.394(a), 35.396(b) and (c), 35.490(a), 35.590(a), and 35.690(a) and (c) on or before October 25, 2005. A licensee shall implement the requirement in § 35.14(a) to provide to the Commission a copy of written attestation(s), signed by a preceptor, on or before October 25, 2005.

* * * * *

5. In § 35.13, paragraphs (b)(1) and (b)(3) are revised to read as follows:

§ 35.13 License amendments.

* * * * *

(b) * * *

(1) For an authorized user, an individual who meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), 35.690(a), 35.910(a), 35.920(a), 35.930(a) and 35.390(b)(1)(ii)(G), 35.392, 35.394, 35.940(a), 35.950(a), or 35.960(a) and 35.690(c);

* * * * *

(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.59 and 35.51(a) and (c); or §§ 35.59 and 35.961(a) or (b);

* * * * *

6. In § 35.14, paragraph (a) is revised to read as follows:

§ 35.14 Notifications.

(a) A licensee shall provide the Commission a copy of the board certification and the written attestation(s), signed by a preceptor, the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, or the permit issued by a Commission master material license broad scope permittee for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under § 35.13(b). For individuals permitted to

work under § 35.13(b)(4), within the same 30 day time frame, the licensee shall also provide, as appropriate, verification of completion of;

(1) Any additional case experience required in § 35.390(b)(1)(ii)(G) for an authorized user under § 35.300;

(2) Any additional training required in § 35.690(c) for an authorized user under § 35.600; and

(3) Any additional training required in § 35.51(c) for an authorized medical physicist.

* * * * *

7. In § 35.50, paragraph (a), the introductory text of paragraph (b)(1)(i), paragraphs (b)(1)(ii)(G), and (c) are revised, paragraph (b)(2) is removed and reserved, and paragraphs (d) and (e) are added to read as follows:

§ 35.50 Training for Radiation Safety Officer.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (d) and (e) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

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

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

(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics–

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.290, 35.390, or, before October 24, 2005, §§ 35.920, or 35.930; and

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(b) * * *

(1) * * *

(i) 200 hours of classroom and laboratory training in the following areas–

(ii) * * *

(G) Disposing of byproduct material; or

(2) [Reserved]

(c)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.51(a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in paragraphs (d) and (e) of this section; or

(2) 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; and,

(d) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (e) and in paragraphs (a)(1)(i) and (a)(1)(ii) or (a)(2)(i) and (a)(2)(ii) or (b)(1) or (c)(1) of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

(e) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

8. In § 35.51, paragraphs (a) and (b) are revised, and paragraph (c) is added to read as follows:

§ 35.51 Training for an authorized medical physicist.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(2) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

(2) Have 2 years of full-time practical training and/or supervised experience in medical physics –

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in §§ 35.490 or 35.690, or, before October 24, 2005, authorized users who meet the requirements in §§ 35.940 or 35.960;

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

(b)(1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical 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 type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must 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 treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (2), or (b)(1) and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51, or, before October 24, 2005, § 35.961, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(c) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

9. In § 35.55, paragraphs (a), (b)(1)(i), and (b)(2) are revised to read as follows:

§ 35.55 Training for an authorized nuclear pharmacist.

* * * * *

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

(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 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

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

(b) * * *

(1) * * *

(i) 200 hours of classroom and laboratory training in the following areas–

* * * * *

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), (a)(2), and (a)(3) or (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

10. Section 35.57 is revised to read as follows:

§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

(a)(1) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002, need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively.

(2) An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002 and [insert date 30 days after publication in the Federal Register] need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively.

(b)(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or

Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2002, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D through H of this part.

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002 and [insert date 30 days after publication in the Federal Register], need not comply with the training requirements of Subparts D through H of this part.

§ 35.75 [Amended]

11. In § 35.75, paragraph (a), footnote 1, remove "(draft)".

12. In § 35.100, paragraph (b)(2) is revised to read as follows:

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

* * * * *

(b) * * *

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920; or

* * * * *

13. In § 35.190, paragraphs (a), the introductory text of (c)(1), (c)(1)(ii)(B) and (c)(2) are revised to read as follows:

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

* * * * *

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

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

(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

* * * * *

(c) * * *

(1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, 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–

(ii) * * *

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

* * * * *

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, 35.390, or, before October 24, 2005, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

14. In § 35.200, paragraph (b)(2) is revised to read as follows:

§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

* * * * *

(b) * * *

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920; or

* * * * *

15. In § 35.290, paragraphs (a), (b), the introductory text of (c)(1) and (c)(1)(ii), (c)(1)(ii)(B), and (c)(2) are revised to read as follows:

§ 35.290 Training for imaging and localization studies.

* * * * *

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

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section;

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

(b) Is an authorized user under § 35.390 and meets the requirements in § 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements; or

(c)(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, 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–

* * * * *

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290, or 35.290(c)(1)(ii)(G) and 35.390, or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements, involving–

* * * * *

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

* * * * *

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

16. In § 35.390, paragraph (a), the introductory text of paragraphs (b)(1) and (b)(1)(ii), paragraphs (b)(1)(ii)(B), (b)(1)(ii)(G)(1), (3) and (4), and (b)(2) are revised, and paragraph (b)(1)(ii)(F) is removed and reserved.

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

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in

paragraphs (b)(1)(ii)(G) and (b)(2) of this section. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs (b)(1)(i) through (b)(1)(ii)(E) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association;

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or

(b)(1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include–

* * * * *

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b) or, before October 24, 2005, § 35.930(b), must also have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involve–

* * * * *

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

* * * * *

(F) [Reserved]

(G) * * *

(1) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

* * * * *

(3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

(4) Parenteral administration of any other radionuclide, for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) and (b)(1)(ii)(G) or (b)(1) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in § 35.390, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), or, before October 24, 2005, § 35.930(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status.

17. In § 35.392, paragraphs (a), (c)(2)(ii) and (c)(3) are revised to read as follows:

§ 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).

* * * * *

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section and whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.); or

* * * * *

(c) * * *

(2) * * *

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

* * * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.392, or 35.394, or, before October 24, 2005, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2).

18. In § 35.394, paragraphs (a), (c)(2)(ii) and (c)(3) are revised to read as follows:

§ 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).

* * * * *

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section, and whose certification has been recognized by the Commission or an Agreement State, and who meets the requirements in paragraph (c)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.); or

* * * * *

(c) * * *

(2) * * *

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

* * * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390 or 35.394, or, before October 24, 2005, §§ 35.930 or 35.934, or equivalent Agreement State requirements. A preceptor authorized

user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2).

19. Section 35.396 is added to read as follows:

§ 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

Except as provided in § 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who–

(a) Is an authorized user under § 35.390 or, before October 24, 2005, § 35.930 for uses listed in §§ 35.390(b)(1)(ii)(G)(3) or 35.390(b)(1)(ii)(G)(4), or equivalent Agreement State requirements; or

(b) Is an authorized user under §§ 35.490 or 35.690, or, before October 24, 2005, §§ 35.940 or 35.960, or equivalent Agreement State requirements and who meets the requirements in paragraph (d) of this section; or

(c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 35.490 or 35.690, or, before October 24, 2005, §§ 35.940 or 35.960; and who meets the requirements in paragraph (d) of this section.

(d)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include–

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390 or 35.396, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in §§ 35.390 or 35.930 must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4). The work experience must involve–

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

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

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

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

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

(vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV and/or

at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.396, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390, or, before October 24, 2005, § 35.930, must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4).

20. In § 35.490, paragraphs (a), (b)(2) and (b)(3) are revised to read as follows:

§ 35.490 Training for use of manual brachytherapy sources.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State, and who meets the requirements in paragraph (b)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council

for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(b) * * *

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490, or, before October 24, 2005, § 35.940, 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 (b)(1)(ii) of this section; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in § 35.490, or, before October 24, 2005, § 35.940, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), or (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.

21. In § 35.491, paragraph (b)(3) is revised to read as follows:

§ 35.491 Training for ophthalmic use of strontium-90.

* * * * *

(b) * * *

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.490 or 35.491, or, before October 24, 2005, §§ 35.940 or 35.941, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

22. In § 35.590, paragraphs (a) and (b) are revised and paragraph (c) is added to read as follows:

§ 35.590 Training for use of sealed sources for diagnosis.

* * * * *

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (b) and (c) of this section and whose certification has been recognized by the Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.); or

(b) 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; and

(c) Has completed training in the use of the device for the uses requested.

23. In § 35.690, paragraphs (a), (b)(2) and (b)(3) are revised, and paragraph (c) is added to read as follows:

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

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(3) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(b) * * *

(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in § 35.690, or, before October 24, 2005, § 35.960, 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 (b)(1)(ii) of this section; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) or (b)(1) and (b)(2), and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in § 35.690, or, before October 24, 2005, § 35.960, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a 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 type(s) of use for which the individual is seeking authorization.

24. In § 35.980, paragraph (b)(2) is revised to read as follows:

§ 35.980 Training for an authorized nuclear pharmacist.

* * * * *

(b) * * *

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Dated at Rockville, Maryland, this _____ day of _____ , 2005.

For the Nuclear Regulatory Commission.

_____

Annette Vietti-Cook,

Secretary of the Commission.

Organization of Agreement States

Stanley Fitch, Chair, New Mexico
Jared Thompson, Chair-Elect, Arkansas
Pearce O'Kelley, Past Chair, South Carolina
Gary Robertson, Treasurer, Washington
Kenneth Weaver, Secretary, Colorado

September 3, 2004

DOCKETED
USNRC

September 29, 2004 (4:26PM)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

PRM - 35-17

Annette L. Vietti-Cook, Secretary
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Attention: Rulemakings and Adjudications Staff

Dear Mrs. Vietti-Cook:

On behalf of the Organization of Agreement States (OAS) and pursuant to 10 CFR 2.802, the enclosed petition is submitted to the U.S. Nuclear Regulatory Commission (NRC) to amend 10 CFR 35.55, 10 CFR 35.190, 10 CFR 35.290 and 10 CFR 35.390. The purpose of this petition is to define and specify the minimum number of didactic (classroom and laboratory) training hours for the Authorized Nuclear Pharmacist and the Authorized Users identified in these sections.

The OAS has developed a Position Statement regarding 10 CFR Part 35 Training and Education requirements identified in 10 CFR 35.55, 10 CFR 35.190, 10 CFR 35.290 and 10 CFR 35.390. In the current rule, the minimum numbers of didactic training hours for radiation safety training are not specified or separated from the total training hours. The current Subpart J does specify a minimum number of classroom and laboratory training hours and supervised work experience.

The Training and Education requirements of Part 35 have been designated as a Category B by the NRC, for Agreement State compatibility in an attempt to provide nationwide "consistency and uniformity." The higher the compatibility classification, the more prescriptive, and more specific the rule text must be to ensure that all Agreement States and NRC Regions be uniform and consistent. The lack of clearly defined didactic training hours for these rule sections weakens the current rule's consistency and uniformity.

The OAS believes that the need for specified didactic training hours is a radiation safety issue rather than a "practice of medicine" issue. Radiation safety for the patient and the occupational radiation workers may likely be compromised. A majority of radiation safety principles and procedures are learned during this important and necessary classroom and laboratory training.

The OAS Executive Board unanimously approved the Position Statement and presented it to the membership for approval. An overwhelming majority (30 of 33) of the Agreement States approved this Position Statement and Petition for Rulemaking. Enclosed is the originally signed OAS Position Statement from the Agreement States requesting this petition for rulemaking.

The petitioner, OAS, requests that the Commission define and specify the minimum number of didactic training hours for the authorized users identified in 10 CFR 35.55, 10 CFR 35.190, 10 CFR 35.290 and 10 CFR 35.390. The clarification of the rule is necessary to ensure consistency and uniformity for medical users nationwide. The Commission should work closely with the stakeholders and Agreement States to achieve a resolution to this problem with the training and education requirements.

It is the desire of OAS to promote an NRC/Agreement State partnership for the development and implementation of uniform and consistent regulations that promote and protect public health and safety. Thank you for your consideration.

Sincerely,

Stanley A. Fitch, Chair
Organization of Agreement States
P.O. Box 913
Sandia Park, New Mexico 87047-0913

Jared W. Thompson, Chair-Elect
Organization of Agreement States
Arkansas Department of Health
4815 W. Markham, Mail Slot 30
Little Rock, Arkansas 72205

cc: Kenneth L.K. Weaver, Secretary
Organization of Agreement States

Paul H. Lohaus, Director
NRC Office of State and Tribal Programs

Organization of Agreement States

PETITION FOR RULEMAKING

The Organization of Agreement States (OAS) submits this petition for rulemaking pursuant to 10 CFR 2.802. It is patterned after the layout and structure of previously submitted petitions accepted by the U.S. Nuclear Regulatory Commission (NRC). The petitioner request the NRC, following notice and opportunity for comment, amend 10 CFR Part 35.55, *Training for an authorized nuclear pharmacist*, 10 CFR 35.190, *Training for uptake, dilution, and excretion studies*, 10 CFR 35.290, *Training for imaging and localization studies*, and 10 CFR 35.390, *Training for use of unsealed byproduct material for which a written directive is required,* to define and specify the number of didactic (classroom and laboratory) training hours in radiation safety required for authorized users and pharmacists.

I. STATEMENT OF PETITIONER'S INTEREST

The OAS is a nonprofit, voluntary, scientific and professional society incorporated in the District of Columbia. The membership of OAS consists of state radiation control directors and staff from the 33 Agreement States who are responsible for implementation of their respective radioactive materials programs. The purpose of the OAS is to provide a mechanism for these Agreement States to work with each other and with the NRC on regulatory issues associated with their respective agreements.

Agreement States are those states that have entered into an effective regulatory discontinuance agreement with the NRC under subsection 274b. of the Atomic Energy Act (AEA). The role of the Agreement States is to regulate most types of radioactive material in accordance with the compatibility requirements of the AEA. These types of radioactive materials include source material (uranium and thorium), reactor fission byproducts, and quantities of special nuclear materials (SNM) not sufficient to form a critical mass. The NRC periodically reviews the performance of each Agreement State to assure compatibility with NRC's regulatory requirements.

Agreement States issue radioactive material licenses, promulgate regulations, and enforce those regulations under the authority of each individual state's laws. The Agreement States exercise their licensing and enforcement actions under direction of their governors in a manner that is compatible with the licensing and enforcement programs of the NRC. The Agreement States currently license and regulate approximately 16,800 radioactive materials licenses, whereas the NRC regulates approximately 4,400 licenses.

Petition for Rulemaking: Amending Training and Education Requirements in Sections of 10 CFR Part 35.

II. BACKGROUND

The NRC revised 10 CFR Part 35, *Medical Use of Byproduct Material*, on April 24, 2002 to make the rule more risk-informed and performance based. The revised training and experience requirements specified in 35.55 (Authorized Nuclear Pharmacists), 35.290 (Authorized Users for Imaging and Localization Studies), and 35.390 (Authorized Users for unsealed byproduct material which requires a written directive) include completion of 700 hours of training and experience. The revised training and experience requirements specified in 35.190 (Authorized Users for uptake, dilution and excretion studies) include completion of 60 hours of training and experience. These sections require said training and experience to include "classroom and laboratory training" and supervised "work experience"; however, there is no specified breakdown, or division, of these hours. The current rule specified in Subpart J, does specify a breakdown of hours between classroom and laboratory training and supervised work experience.

10 CFR Part 35.55, *Training for an authorized nuclear pharmacist,* requires the accepted boards to require the same 700 total hours of didactic and supervised practical experience hours as specified in 35.55.b for the alternative pathway. It does not specify a breakdown of the didactic training hours in radiation safety.

10 CFR 35.190, *Training for uptake, dilution, and excretion studies*, requires the accepted boards to require the same 60 total hours specified in the alternative pathway (35.190.c). The wording of the text refers to the description of the hours in 35.190.c.1. Paragraph 35.190.c.1 states, "Has completed 60 hours of training and experience in basic radionuclide handling techniques....". It does not specify a breakdown of the didactic training hours in radiation safety.

10 CFR 35.290, *Training for imaging and localization studies*, requires the accepted boards to require the same 700 hours specified in the alternative pathway (35.290.c). The wording of the text refers to the description of the hours in 35.290.c.1. Paragraph 35.290.c.1 states "Has completed 700 hours of training and experience in basic radionuclide handling techniques..." It does not specify a breakdown of the didactic training hours in radiation safety.

10 CFR 35.390, *Training for use of unsealed byproduct material for which a written directive is required,* requires the accepted boards to require the same 700 hours specified in the alternative pathway (35.390.b). The wording of the text refers to the description of the hours in 35.390.b.1. Paragraph 35.390.b.1 states "Has completed 700 hours of training and experience in basic radionuclide handling techniques..." It does not specify a breakdown of the didactic training hours in radiation safety.

Petition for Rulemaking: Amending Training and Education Requirements in Sections of 10 CFR Part 35.

III. Proposed Actions

10 CFR Part 35.55, *Training for an authorized nuclear pharmacist*, 10 CFR 35.190, *Training for uptake, dilution, and excretion studies*, 10 CFR 35.290, *Training for imaging and localization studies*, and 10 CFR 35.390, *Training for use of unsealed byproduct material for which a written directive* be amended to define and specify the number of didactic training hours in radiation safety for these pharmacists and medical authorized users.

It is recommended that the training and experience requirements for 35.55, 35.190, 35.290, and 35.390 be revised to specify a breakdown of the total training hours into didactic (classroom and laboratory) training and supervised work experience. This will clarify that radiation safety, which is clearly within the Agreement States and NRC's purview, rather than clinical skills, are the focus of the regulatory requirements.

The amended rules will ensure adequate radiation safety training for Authorized Users, Radiation Safety Officers and Authorized Nuclear Pharmacists and ensure consistency and uniformity of training requirements nationwide.

IV. RATIONALE FOR THE CHANGES

OAS believes that the need for specific didactic training hours is not a "practice of medicine issue" but it is a radiation safety training issue.

The revised rules are less prescriptive, and rely more on the knowledge and performance of Radiation Safety Officers, Authorized Users, Authorized Medical Physicists and Authorized Nuclear Pharmacists to maintain adequate radiation safety programs. Therefore the safe use of radioactive material in medicine now relies primarily on the various training and experience requirements specified in Part 35. Since radiation safety is the goal of these related regulations, consideration must be given to the methods by which an Authorized User, Radiation Safety Officer or Authorized Nuclear Pharmacist receives radiation safety training. The majority of basic radiation safety principles are learned in the didactic portion of training, not with "work experience". In addition, proper didactic training programs will better prepare the individual for out of the ordinary occurrences that are not likely to be seen during supervised work experience. An appropriate didactic training program should supplement the supervised work experience portion so that the individual understands how radiation safety integrates into the practice of medicine. If an Authorized User or Radiation Safety Officer is not adequately trained in radiation safety that person cannot effectively supervise the safe use of radioactive material.

Petition for Rulemaking: Amending Training and Education Requirements in Sections of 10 CFR Part 35.

While the OAS is unaware of any documentation of major inconsistencies in the Agreement State implementation of the old Training and Experience requirements, the Training and Experience requirements of the revised Part 35 have been designated as "Category B" for Agreement State compatibility in an attempt to provide nationwide "consistency and uniformity" of authorized user credentialing. The higher the compatibility classification, the more prescriptive, and more specific the rule text must be to ensure that all Agreement States and NRC Regions can be uniform and consistent. The lack of clearly defined didactic training hours for these authorized users weakens the rule's consistency and uniformity.

By not specifying a minimum number of didactic training hours in these paragraphs, radiation safety is likely compromised, leading to a weakening of the effectiveness of Part 35 to adequately assure the radiation safety of the patient, the occupationally exposed worker, and the public. In addition, the effort to develop a consistent and uniform set of standards has been weakened. Consistency is necessary so that Agreement States and NRC Regional offices can accept each other's approved authorized users. The lack of clearly define training requirements will negatively impact the effective implementation of these standards nationwide.

With the less prescriptive nature of the rules, Agreement States are being required to adopt rules that are viewed as inadequate. Without adequate didactic training, an individual's knowledge of basic radiation safety physics, radiation biology, and radiopharmaceutical chemistry may be lacking. Agreement States are concerned that by using less prescriptive rules, they may likely compromise their citizens to individuals who have not received adequate radiation safety training. In the interest of public health and safety, clearly defined and specified didactic training hours must be codified.

Currently, Agreement States review all third party didactic radiation safety training programs. For example, even though the NRC changed the training and experience criteria for nuclear pharmacists some years ago, Agreement States have continued to use the previous criteria for didactic training (200 hours) when reviewing the adequacy of a new program. As a result, all current nuclear pharmacists have received at least 200 hours of didactic training in the required subject matter. Were the revised rules to be adopted under compatibility B requirements, it is possible that not all didactic training programs would be reviewed using the same criteria, and most likely this would result in a training program not being universally accepted by all Agreement States. Specifying the minimum number of didactic training hours in the rule assures consistency and uniformity in the review of these programs, as well as resulting in uniform and consistent acceptance, in all states, of an approved didactic training program.

Petition for Rulemaking: Amending Training and Education Requirements in Sections of 10 CFR Part 35.

OAS presents this petition for rulemaking within its natural progression to represent the collective principles of its members regarding regulatory standards. Attached is a copy of the OAS Position Statement signed by 30 of the Agreement States in support of this Petition for Rulemaking.

V. CONCLUSION

The proposed amended sections of 10 CFR Part 35 will provide a formal, more structured approach to ensure consistent implementation of the rules nationwide. Defined and specified didactic training hours and supervised clinical training hours will better ensure adequate radiation safety training for Authorized Users and Authorized Nuclear Pharmacists. Therefore, radiation safety will be improved for the licensees, authorized users, the patients, occupationally exposed workers and the public.

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Organization of Agreement States

Organization of Agreement States, Inc. (OAS)
POSITION PAPER AND PETITION FOR RULEMAKING

Regarding 10CFR Part 35 Mandated Training and Experience Requirements and Medical Didactic Training Hours

The Nuclear Regulatory Commission (NRC) revised 10CFR Part 35, effective October 24, 2002, to make the rule more risk-informed and performance based. The revised rules are less prescriptive, and rely more on the knowledge and performance of Radiation Safety Officers, Authorized Users, Authorized Medical Physicists and Authorized Nuclear Pharmacists to maintain adequate radiation safety programs. Therefore the safe use of radioactive material in medicine now relies primarily on the various training and experience requirements specified in Part 35.

The revised training and experience requirements specified in 35.55 (Authorized Nuclear Pharmacists), 35.290 (Authorized Users for Imaging and Localization Studies), and 35.390 (Authorized Users for unsealed byproduct material which requires a written directive) include completion of 700 hours of training and experience. The revised training and experience requirements specified in 35.190 (Authorized Users for uptake, dilution and excretion studies) include completion of 60 hours of training and experience. These sections require said training and experience to include "classroom and laboratory training" and supervised "work experience"; however, there is no specified breakdown, or division, of these hours. Previously, the rules did specify a breakdown of hours between classroom and laboratory training and supervised work experience.

OAS supports its membership in defining and implementing consensus standards on the medical use of radionuclides in the Agreement States that (respective to the October 24, 2002 revision of Part 35):

- better ensure adequate radiation safety training for Authorized Users, Radiation Safety Officers and Authorized Nuclear Pharmacists;
- specify the acceptable breakdown of didactic and supervised clinical training hours; and,
- improve and ensure consistency and uniformity of training requirements.

Since radiation safety is the goal of any related regulation, consideration must be given to the methods by which an Authorized User, Radiation Safety Officer or Authorized Nuclear Pharmacist receives radiation safety training. The majority of basic radiation safety principles are learned in the didactic portion of training, not with "work experience". If an Authorized User or Radiation Safety Officer is not adequately trained in radiation safety, that person cannot effectively supervise the safe use of radioactive material.

By not specifying a minimum number of didactic training hours:

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- The effort to develop a consistent and uniform set of standards has been weakened.

The Agreement States have regulatory authority over nearly 80% of the byproduct licensees nationwide. It is incumbent upon the Agreement States to assure adequate radiation safety under these licenses. The membership of the OAS has expressed profound concern that by being required to accept diminished didactic training requirements, the Agreement States are forced to the possible jeopardy of subjecting their citizens to users who have not received adequate radiation safety training.

OAS presents this position statement within its natural progression to represent the collective principles of its members regarding regulatory standards. As a leader in nationwide radiation safety, OAS also seeks to facilitate effective participation of Agreement States in the National Materials Program.

By my signature below, I certify that I am a member of the OAS and confirm my agreement with this position paper. Further, I petition the NRC for a rulemaking to include a breakdown of didactic and supervised clinical hours required in the alternative training pathways for authorized nuclear pharmacists (35.55) and authorized users (35.190, 35.290, and 35.390).

Kathy E. Whatley 7/13/04 — Name and Position

Alabama — State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.

Organization of Agreement States

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Regarding 10CFR Part 35 Mandated Training and Experience Requirements and Medical Didactic Training Hours

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By not specifying a minimum number of didactic training hours:

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The Agreement States have regulatory authority over nearly 80% of the byproduct licensees nationwide. It is incumbent upon the Agreement States to assure adequate radiation safety under these licenses. The membership of the OAS has expressed profound concern that by being required to accept diminished didactic training requirements, the Agreement States are forced to the possible jeopardy of subjecting their citizens to users who have not received adequate radiation safety training.

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Jared W. Thompson Prog Mgr/RSO/NVA — Arkansas — 7/26/04

Name and Position — State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.

Organization of Agreement States

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Dan Kuehl ARRA — Name and Position

7/20/04 — State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.

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Jared W. Thompson, Program Leader — Arkansas

Name and Position — State

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Kim Clubbock, Health Physicist — Arkansas

Name and Position — State

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State of California—Health and Human Services Agency

Department of Health Services

SANDRA L. SHEWRY
Director

ARNOLD SCHWARZENEGGER
Governor

FACSIMILE COVER SHEET

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DATE: 8/03/04

TOTAL NUMBER OF PAGES INCLUDING COVER SHEET: 2

TO: Jared W Thompson

COMPANY: OAS

~~PHONE~~ Fax: (501) 661-2849 FAX: (___)

FROM: Ed Bailey

PHONE: (916) 440-7899 FAX: (___)

[ ] URGENT!!! [ ] PER YOUR REQUEST [ ] PLEASE COMMENT

COMMENTS:

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Logan A. Stanley — CHIEF, CALIFORNIA RAD. HEALTH BRANCH — CALIFORNIA

8-3-2004

Name and Position — State

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Radiation Control

Regarding 10CFR Part 35 Mandated Training and Experience Requirements and Medical Didactic Training Hours

The Nuclear Regulatory Commission (NRC) revised 10CFR Part 35, effective October 24, 2002, to make the rule more risk-informed and performance based. The revised rules are less prescriptive, and rely more on the knowledge and performance of Radiation Safety Officers, Authorized Users, Authorized Medical Physicists and Authorized Nuclear Pharmacists to maintain adequate radiation safety programs. Therefore the safe use of radioactive material in medicine now relies primarily on the various training and experience requirements specified in Part 35.

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Craig L Bergdolt — Director
Name and Position
Hazardous Materials & Waste Management Division

Colorado
State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.

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Organization of Agreement States

Organization of Agreement States, Inc. (OAS)
POSITION PAPER AND PETITION FOR RULEMAKING

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William A. Passetti, BUREAU CHIEF — FLORIDA

Name and Position — State

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Undecided Georgia

Jared Thompson

From: Cynthia Sanders [CSanders@dnr.state.ga.us]
Sent: Thursday, July 29, 2004 4:28 PM
To: Jared Thompson
Subject: RE: OAS Position Statement

Jared,

I spoke with David Walters regarding the OAS Position Statement. At this time, I am still not comfortable signing it. I prefer to hold off on this until further discussions at the OAS annual meeting.

Cynthia Sanders

>>> "Jared Thompson" <jwthompson@HealthyArkansas.com> 7/26/2004 10:51:20 AM >>>

> To: Members of the Organization of Agreement States (OAS)
>
Please review the attached Proposed OAS Position Statement on Part 35 Didactic Training Hours. Your response regarding this Position Statement is important. The OAS Board would like to present as many signed statements to the Commission on August 17, 2004. This effort at unity will strengthen our standing with NRC staff and the Commission.

Please return the signed Position Statement to me ASAP. You can fax a copy to me at 501-661-2849, but please mail your signed original. The Part 35 Ad Hoc Committee will be contacting you, if we do not receive a response. We are looking for 100% response from Director Members.

If you have already responded.....THANK YOU!!!!!!!!!!!!!!!!!!!

Jared Thompson

> On May 26, 2004, the OAS held a meeting in conjunction with the CRCPD
> meeting in Bloomington, Minnesota to discuss Part 35 the didactic training
> issue. Jared Thompson, OAS Chair-Elect facilitated the meeting, where 24 of
> the 33 Agreement States were represented. A consensus opinion was reached
> that a minimum number of didactic hours should be specified for Authorized
> Nuclear Pharmacists and the Authorized Users of 35.100, 35.200 and 35.300
> materials. It was also agreed that the OAS should petition the NRC for
> rulemaking on Part 35 to provide more consistent and uniform training rules.
>
> Those in attendance at the May 26 meeting determined that OAS should
> complete the following action items:
> -- Finalize a position paper for developing consensus among the 33 Agreement
> States regarding the need for establishment of a minimum number of didactic
> training hours for Authorized Nuclear Pharmacist and Authorized Users of
> 35.100, 35.200 and 35.300 materials.
> -- Include in the position paper a petition for rulemaking to the NRC
> regarding the establishment of a minimum number of didactic training hours
> for Authorized Nuclear Pharmacist and Authorized Users of 35.100, 35.200 and
> 35.300 materials.
>
> In accordance with these action items, the OAS Part 35 Ad Hoc Working Group
> completed a position statement that integrated the petition for rulemaking.
>
> Please review the attached Position Statement. Your input is requested.
> Please read the statement, and if you agree with its declarations,
> please complete the portion that petitions NRC for rulemaking
> and send to Jared Thompson at the address indicated on the form. Please
> send to Jared no later than July 30, 2004. The OAS Executive Board will
> deliver the position statement and petitions to the NRC Commissioners during
> our briefing with them on August 17, 2004. Time is of the essence.

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Gary M. Wright - Asst Director DERA — Name and Position

Illinois — State

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Donald C. Flater, Chief, BRH — Name and Position

Iowa — State

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Radiation Control

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Name and Position

Kansas
State

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Robert L. Johnson, Program Administrator — Name and Position

Kentucky — State

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Michael E. Henry, CRCPD DIRECTOR/MEMBER — Name and Position

7/9/04 — State

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Program Manager — Name and Position

MAINE — State

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By not specifying a minimum number of didactic training hours:

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Robert Walker, Director
MA Radiation Control Program
Name and Position

July 12/04
State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.

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Robert W. Goff, Director: Radiological Health — Name and Position

Mississippi — State

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Name and Position: Radiation Control Program Manager

State: Nebraska

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KENNY C. GUINN
Governor

MICHAEL J. WILLDEN
Director

YVONNE SYLVA
Administrator

BRADFORD LEE, M.D.
State Health Officer

STATE OF NEVADA
DEPARTMENT OF HUMAN RESOURCES
HEALTH DIVISION
BUREAU OF HEALTH PROTECTION SERVICES

] Bureau Administration
1179 Fairview Drive, Ste. 201
Carson City, NV 89701-5405
(775) 687-6353
Fax (775) 687-5197

] Public Health Engineering
1179 Fairview Drive, Ste. 101
Carson City, NV 89701-5405
(775) 687-4754
Fax (775) 687-5699

] Drinking Water
State Revolving Fund
1179 Fairview Drive, Ste. 204
Carson City, NV 89701-5405
(775) 687-4750
Fax (775) 687-3218

] Radiological Health
1179 Fairview Drive, Ste. 102
Carson City, NV 89701-5405
(775) 687-5394
Fax (775) 687-5751

] Environmental Health
1179 Fairview Drive, Ste. 104
Carson City, NV 89701-5405
(775) 687-4750
Fax (775) 687-5751

] Health Protection Services
620 Belrose Street, Ste. 101
Las Vegas, NV 89107
Engineering and Food
(702) 486-5068
Radiological Health
(702) 486-5280
Fax (702) 486-5024

Health Protection Services
850 Elm Street
Elko, NV 89801-3349
(775) 753-1138/1140

Health Protection Services
475 W. Haskell Street, Rm. 38
Winnemucca, NV 89445
(775) 623-6588

Health Protection Services
155 N. Taylor Street, Ste. 199
Fallon, NV 89406-3324
(775) 423-2281
Fax (775) 428-0259

Health Protection Services
P.O. Box 151210
Ely, NV 89315
(775) 289-3325

Health Protection Services
P.O. Box 667
Tonopah, NV 89049-0667
(775) 482-3997

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From: Marshall, Nevada

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Radiation Control and Emergency Mgmt

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"Building and Strengthening Public Health through Communication and Partnerships"

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POSITION PAPER AND PETITION FOR RULEMAKING

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Stanley R. Marshall — Radiological Health Chief
Name and Position

Nevada — July 26, 2004
State

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REC'D AUG 12 2004

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Dennis P. O'Dowd

Dennis P. O'Dowd, Acting Administrator
Radiological Health Section
Division of Public Health Services

Name and Position

New Hampshire

State

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John Saulsberry, Bureau Chief — New Mexico

Name and Position — State

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Stanley Fitch, Health Physicist 7-6-04 — New Mexico

Name and Position — State

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Margaret M. Doyle - RAM Licensing — Name and Position

New Mexico Radiation Control Bureau — State

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Cidela Salame-Alfie
Name and Position

New York State Dept of Health
State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.

Organization of Agreement States

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Radiation Control and Emergency Mgt.

Organization of Agreement States, Inc. (OAS)
POSITION PAPER AND PETITION FOR RULEMAKING

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Name and Position	State
DIRECTOR OFFICE OF RAD. HEALTH	NEW YORK CITY – N.Y. AGREEMENT

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Clayton Brandt

Name and Position

CLAYTON BRANDT PRINCIPAL RADIOPHYSICIST

NYS DEPT. OF LABOR

State

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FAX

TO: Jared Thompson

FAX#: 501-661-2849

FROM: Beverly O. Hall

DATE: 7-26-04

Page(s): 2, Including cover sheet.

Comments:

OAS Position Statement

Radiation Protection Section
1645 Mail Service Center
Raleigh, NC 27699-1645
☎: (919) 571-4141
🖷: (919) 571-4148

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Russell O. Hall, Chief — July 26, 2004

Name and Position — State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.

Jared Thompson

From: Beverly Hall [beverly.hall@ncmail.net]
Sent: Monday, July 26, 2004 10:25 AM
To: Jared Thompson
Cc: Stanley Fitch
Subject: Re: OAS Position Statement

I am signing this Position statement, however, we are checking with the NC Board of Pharmacy to ensure we have the authority and also, that their will be no conflicts with the Nuclear Pharmacist requirements.

Beverly Hall

Jared Thompson wrote:

> To: Members of the Organization of Agreement States (OAS)
>
> Please review the attached Proposed OAS Position Statement on Part 35 D
>
> Please return the signed Position Statement to me ASAP. You can fax a
>
> If you have already responded.....THANK YOU!!!!!!!!!!!!!!!!!!
>
> Jared Thompson
>
> On May 26, 2004, the OAS held a meeting in conjunction with the CRCPD meeting in Bloomington, Minnesota to discuss Part 35 the didactic training issue. Jared Thompson, OAS Chair-Elect facilitated the meeting, where 24 the 33 Agreement States were represented. A consensus opinion was reached that a minimum number of didactic hours should be specified for Authorized Nuclear Pharmacists and the Authorized Users of 35.100, 35.200 and 35.300 materials. It was also agreed that the OAS should petition the NRC for rulemaking on Part 35 to provide more consistent and uniform training rule
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> -- Finalize a position paper for developing consensus among the 33 Agreeme States regarding the need for establishment of a minimum number of didacti training hours for Authorized Nuclear Pharmacist and Authorized Users of 35.100, 35.200 and 35.300 materials.
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> In accordance with these action items, the OAS Part 35 Ad Hoc Working Grou completed a position statement that integrated the petition for rulemaking
>
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Ark. Dept. of Health
Radiation Control and Emergency Mgt

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Terry O'Clair, Director, Air Quality Div. — North Dakota

Name and Position — State

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Jared Thompson

OHDO

From: Robert Owen [ROWEN@gw.odh.state.oh.us]
Sent: Wednesday, August 04, 2004 4:22 PM
To: Jared Thompson
Cc: MHOWARD@gw.odh.state.oh.us
Subject: RE: OAS Position Statement

NO

Jared, I believe more work needs to be done among ourselves and in conjunction with NRC in order to flush out what the training hours needs to be. I certainly don't support moving forward with a rule petition, since that demonstrates a final position on the part of OAS. Even among ourselves there are differences of opinion.

I am also unconvinced that we are at a point of arriving at a final position statement without studying the issues via a working group in a cooperative effort, resulting in a position paper that is adoptable by all of OAS. I believe a consensus position is what the National Materials Program would dictate, and that includes NRC at the table, ultimately.

I realize that NRC went ahead and adopted their standard pursuant to ACMUI and not necessarily factoring in OAS concerns. I'm not sure on that point. However, I don't believe we should reciprocate.

I'm looking forward to further discussion of the matter at the OAS annual meeting. Hopefully, we can arrive at a true consensus position on the matter. If not, then further work needs to be done in that direction.

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AUG 0 6 2004

Ark. Dept. of Health
Radiation Control and Emergency Mgt

Thanks for the opportunity to comment.

Bob

-----Original Message-----
From: ODH_REMOTE.GWIA."jwthompson@HealthyArkansas.com"
Sent: Monday, July 26, 2004 10:51 AM
To: Robert Owen; agodwin@arra.state.az.us; asa01@health.state.ny.us; bayoungb@gw.dec.state.ny.us; beverly.hall@ncmail.net; bill_passetti@doh.state.fl.us; Bob.Walker@state.ma.us; clayton.bradt@labor.state.ny.us; csanders@dnr.state.ga.us; dfinerfrock@utah.gov; dflater@idph.state.ia.us; dodowd@dhhs.state.nh.us; Eastvold@iema.state.il.us; EBailey@dhs.ca.gov; eddie.nanney@state.tn.us; gary.robertson@DOH.WA.GOV; gmiskin@health.nyc.gov; jackf@doh.state.ri.us; jay.hyland@state.me.us; john_parker@nmenv.state.nmus; julia.schmitt@hhss.state.ne.us; kwangler@state.nd.us; kwhatley@adph.state.al.us; michael.henry@la.gov; Mike.Broderick@deq.state.ok.us; okelletp@dhec.sc.gov; rfletcher@mde.state.md.us; rgoff@msdh.state.ms.us; Richard.Ratliff@tdh.state.tx.us; robertl.johnson@mail.state.ky.us; sjablons@tnrcc.statetx.us; smarshall@nvhd.state.nv.us; Steve.Tarlton@state.co.us; tconley@kdhestate.ks.us; william_floyd@nmenv.state.nm.us
Cc: dwlater@state.al.us; Edwin.L.Wright@state.or.us; kenneth.weaver@state.co.us; kwiebeck@HealthyArkansas.com; stanley_fitch@nmenv.state.nm.us
Subject: RE: OAS Position Statement

> To: Members of the Organization of Agreement States (OAS)
>
Please review the attached Proposed OAS Position Statement on Part 35 Didactic Training Hours. Your response regarding this Position Statement is important. The OAS Board would like to present as many signed statements to the Commission on August 17, 2004. This effort at unity will strengthen our standing with NRC staff and the Commission.

Please return the signed Position Statement to me ASAP. You can fax a copy to me at 501-661-2849, but please mail your signed original. The Part 35 Ad Hoc Committee will be contacting you, if we do not receive a response. We are looking for 100% response from Director Members.

If you have already responded.....THANK YOU!!!!!!!!!!!!!!!!!!!!

Jared Thompson

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> meeting in Bloomington, Minnesota to discuss Part 35 the didactic training
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>
> Please review the attached Position Statement. Your input is requested.
> Please read the statement, and if you agree with its declarations,
> please complete the portion that petitions NRC for rulemaking
> and send to Jared Thompson at the address indicated on the form. Please
> send to Jared no later than July 30, 2004. The OAS Executive Board will
> deliver the position statement and petitions to the NRC Commissioners during
> our briefing with them on August 17, 2004. Time is of the essence.
>
>
> Jared W. Thompson, Chair-Elect
> Organization of Agreement States
>
> Arkansas Department of Health
> Radioactive Materials Program
> 4815 W. Markham, Mail Slot 30
> Little Rock, Arkansas 72205
> 501-661-2173
> 501-661-2849 (fax)
> Do not mistake for conspiracy and intrigue what can best be explained by
stupidity and incompetence.
>
> > <<Didactic_Training_Position_Statement.pdf>>

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Pamela L Bishop ESIV — Oklahoma

Name and Position — State

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Edwin Wright Mgr — OREGON

7/30/04 Name and Position RADIOACTIVE MATERIALS LICENSING State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.

Organization of Agreement States

Organization of Agreement States, Inc. (OAS)

POSITION PAPER AND PETITION FOR RULEMAKING

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JUL 19 2004
Rulemaking Ark. Dept. of Health

Regarding 10CFR Part 35 Mandated Training and Experience Requirements and Medical Didactic Training Hours

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Marie Stockel, Chief, Rad. Control Agency — Name and Position

Rhode Island — State

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Name and Position

South Carolina

State

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Organization of Agreement States

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Richard C. Ratliff, Bureau Chief — Name and Position

Texas — State

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Laurence E. Nanney, Director — Name and Position

Tennessee (Div. of Radiological Hlth) — State

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FAX

DATE: 7-26-04	TIME:	PAGES: Two

TO: Jared Thompson

Radioactive Materials Program
Arkansas Dept. of Health
FAX 501/661-2136

FROM: Craig Jones

State of Utah
Department of Environmental Quality
Division of Radiation Control
168 North 1950 West
Salt Lake City, Utah 84116
(801)536-4250 VOX
(801)533-4097 FAX
(801)536-4414 TDD

Olene S. Walker, Governor
Dianne R. Nielson, Ph.D., Executive Director
Dane L. Finerfrock, Director

SUBJ: 10 CFR 35 Position Statement

COMMENTS

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Gary Robertson Director — Name and Position

WA — State

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REC'D AUG 09 2004

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Paul Schmidt, Chief, RPS — Name and Position

Wisconsin — State

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REGULATORY ANALYSIS

FINAL RULE

10 CFR PART 35 – RECOGNITION OF SPECIALTY BOARDS

BACKGROUND:

The Nuclear Regulatory Commission (NRC) is amending its regulations governing the medical use of byproduct material to change its requirements for recognition of specialty boards whose certifications may be used to demonstrate the adequacy of the training and experience (T&E) of individuals to serve as radiation safety officers (RSOs), authorized medical physicists (AMPs), authorized nuclear pharmacists (ANPs), or authorized users (AUs). The amendments also revise the requirements for demonstrating the adequacy of T&E for pathways other than the board certification pathway. This rulemaking is necessary to address the T&E issue for recognition of specialty board certifications.

During development of revised 10 CFR Part 35, published as a proposed rule on August 13, 1998 (63 FR 43516) and as a final rule on April 24, 2002 (67 FR 20249), there was a general belief that the boards recognized by the NRC would meet, or could make adjustments to meet, the new requirements established by that rulemaking governing recognition of specialty boards by the NRC and that these boards would continue to be recognized by the NRC. However, when applications for recognition were received, the NRC staff determined that, except for one board, the boards did not meet all the requirements in the final rule.

On February 19, 2002, in a briefing of the Commission, the Advisory Committee on Medical Uses of Isotopes (ACMUI) expressed concern that if the revisions to 10 CFR Part 35, approved by the Commission on October 2, 2000 were to become effective as drafted, there could be potential shortages of individuals qualified to serve as RSOs, AMPs, ANPs, and AUs. The ACMUI also expressed the concern that the boards might become “marginalized.” To resolve these concerns, the NRC modified the final rule by reinserting Subpart J (as contained in the proposed rule) for a 2-year period, thereby continuing recognition of the listed boards for a transition period during which the NRC could work to resolve the problem. The final rule was

published in the Federal Register on April 24, 2002 (67 FR 20249), with an effective date of October 24, 2002 and the transition period will end on October 24, 2004. In a Staff Requirements Memorandum (SRM-COMSECY-02-0014) dated April 16, 2002, the Commission instructed the NRC staff to develop options for addressing the T&E issue related to recognition of specialty board certifications.

The ACMUI formed a subcommittee to develop recommendations on this issue. After considering comments on the issue during a public meeting on June 21, 2002, along with letters from stakeholders, the subcommittee developed a final recommendation which was discussed and approved by the ACMUI during a public teleconference meeting on July 8, 2002. The ACMUI submitted recommendations in a report, including suggested rule language, to the NRC on August 1, 2002. The NRC staff provided options for addressing the T&E requirements in SECY-02-0194 dated October 30, 2002. On February 12, 2003, the Commission issued SRM-02-0194, responding to SECY-02-0194, that approved preparation of a proposed rule to modify the T&E requirements, based on the ACMUI's recommendations. The NRC staff prepared a proposed rule and recommended its publication in the Federal Register in SECY-03-0145, dated August 21, 2003. The Commission approved the NRC staff's recommendation to publish the proposed rule, with certain changes directed by the Commission, in SRM-03-0145, dated October 9, 2003. The proposed rule was published for a 75 day comment period on December 9, 2003. The NRC staff briefed the ACMUI on the proposed rule during its meeting on March 2, 2004 and received comments from the ACMUI on the proposed rule during this meeting and a public teleconference conducted on March 22, 2004. Further discussions were held in consultations with the ACMUI and Agreement States on a draft of the final rule during the period of June to October 2004. The NRC staff briefed the ACMUI and received comments on a draft of the final rule during its meeting, conducted via telecon (with Agreement State representatives in attendance) on October 5, 2004 and during its meeting on October 13-14, 2004. These comments were taken into consideration by the NRC during preparation of the final rule.

The Organization of Agreement States (OAS) (petitioner) filed a Petition for Rulemaking (petition) dated September 3, 2004 (PRM-35-17) requesting that the NRC amend 10 CFR §§ 35.55, 35.190, 35.290 and 35.390 to define and specify the minimum number of didactic

(classroom and laboratory) training hours for Authorized Nuclear Pharmacists and Authorized Users identified in these sections. Notice of receipt of the petition was published in the Federal Register on October 28, 2004 (69 FR 62831). The petitioner requested that the NRC amend its regulations to specify the minimum number of didactic (classroom and laboratory) training hours required to meet the requirements for training and experience to qualify as an authorized nuclear pharmacist (§ 35.55) and an authorized user identified in the NRC's regulations on training for uptake, dilution, and excretion studies (§ 35.190); imaging and localization studies (§ 35.290); and use of unsealed byproduct material for which a written directive is required (§ 35.390). As discussed in the **Supplementary Information** for the final rule, the issues raised by the Agreement States in comments on the proposed rule were the same issues as those raised by the petitioner. Because of the similarity in issues raised, the NRC considered the OAS petition as part of this rulemaking. The NRC determined to grant the petition in part, and is revising §§ 35.55, 35.190, 35.290, and 35.390, in the final rule, to establish a requirement for minimum number of hours 'didactic' (classroom and laboratory) training for the alternate pathway. The requirement does not apply to the criteria for recognition of specialty board certification processes. The rationale for this change is explained in the **Supplementary Information** for the final rule. This completes action on PRM-35-17.

Changes in the T&E requirements relate to two of the three pathways for approval of RSOs, AMPs, ANPs, and AUs. The first relates to changes in criteria for recognition of the certifications of specialty boards as being sufficient to meet NRC requirements for T&E, referred to as the "certification pathway." A second pathway, referred to as the "alternate pathway," involves changes to listings of requirements in the rule for T&E for those who do not choose the certification pathway. The principal rule changes involve revising the criteria for the certification pathway so that the requirements are less prescriptive than those in the current rule. The final rule revises the criteria that a board must meet to be recognized by the NRC or an Agreement State. The criteria for RSOs, AMPs, and ANPs include requirements for a degree from an accredited college or university, professional experience, passing an examination administered by the board, and in some cases additional training specific to the type of use (termed "modality" by the ACMUI) for which they would be responsible. On October 9, 2003, the Commission issued SRM-03-0145, responding to SECY-03-0145, that approved publication of the proposed rule to modify the T&E requirements. In that SRM the

Commission approved the ACMUI's recommendation to separate the requirement for obtaining preceptor statements from the board certification and alternate pathways. The final rule requires licensees to submit preceptor statements to the NRC or an Agreement State together with a copy of an individual's board certification. The certification pathway also includes a specification for the number of hours of T&E for ANPs and AUs for uses of certain byproduct material under §§ 35.100, 35.200, 35.300 (in 35.390, 35.392, 35.394, 35.396 for uses under 35.300), and 35.500.

DISCUSSION:

There are three main reasons why the boards listed in Subpart J would no longer be qualified for recognition under 10 CFR Part 35.

1. Training and Experience Requirements

Under the regulations in the former 10 CFR Part 35, boards were not required to meet specific didactic/laboratory T&E requirements to attain NRC recognition. Before a board was listed in Subpart J, the ACMUI reviewed its certification program and determined the adequacy of the program. The T&E provisions of the current 10 CFR Part 35, 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 10 CFR Part 35 for the alternate pathway. This results in situations where the requirements of the board do not match the specific criteria of the current rule.

2. Preceptor Attestation

Under the regulations in the former 10 CFR Part 35, preceptor certification (now termed preceptor attestation in this final rule) was not required for board certification. The current regulations require preceptor certification, including a signature by an authorized individual. This requirement applies to individuals meeting the T&E requirements through either the certification or alternate pathway. Some boards require attestation 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.

3. New Types of Use

The T&E requirements in the current 10 CFR Part 35 were expanded to address two new types of use that were not considered in the former rule (i.e., remote afterloader units and gamma stereotactic radiosurgery units, as described in § 35.690). These requirements were geared to address unique health and safety issues specific to these types of use. However, the boards' programs do not specifically include T&E for the new types of use. This raises a concern as to how existing qualified individuals will obtain and demonstrate competence in radiation safety in a new type of use.

ALTERNATIVES

Only two alternatives are considered in this regulatory analysis: (1) No action -- retaining the T&E requirements of the current 10 CFR Part 35; and (2) carrying out a rulemaking to modify T&E requirements to address the concerns noted above.

Option 1 (No Action) assumes that no regulatory action is undertaken, which would leave the requirements of the T&E sections of 10 CFR Part 35 unchanged, and would require the boards to modify their certification processes as necessary to comply with the specified requirements. However, with the exception of one specialty board, the specialty boards have indicated that they will not modify their certification processes and consequently the boards' certification processes will not be recognized by the NRC after the expiration of Subpart J on October 24, 2004.

When the NRC enacted the current 10 CFR Part 35, the Commission believed that there would be twenty-three specialty boards whose certification processes could be used by individuals seeking authorization as RSOs, AMPs, ANPs, or AUs in order to demonstrate the adequacy of their T&E. However, after October 24, 2004, twenty-two of those specialty boards will no longer be recognized by the NRC or an Agreement State, which effectively eliminates the board

certification pathway as a means for individuals to be authorized as RSOs, AMPs, ANPs, or AUs. The effective elimination of the certification pathway would mean that before candidates could be permitted to work as RSOs, AMPs, ANPs, or AUs they would have to meet the requirements for T&E through the alternate pathway. In order for a candidate to obtain approval via the alternate pathway, a licensee would have to prepare and submit an application for a license amendment, including a preceptor statement for the candidate, and receive NRC approval before the candidate could serve in the capacity for which approval was being sought. (By contrast, pursuant to 10 CFR 35.13(b)(1), licensees do not need to submit an amendment to allow an individual to work as an AMP, ANP, or AU if that individual meets the requirements of the board certification pathway).

As a result, under Option 1, licensees would have to prepare and submit approximately 665 additional license amendments each year, which the NRC and Agreement States would have to review and approve. In addition, there could potentially be a shortage of authorized individuals.

Under Option 2 (Rulemaking, the option pursued), the NRC is implementing a rulemaking to modify the regulations to specify new T&E criteria for recognition of board certification processes. The NRC expects, based on interaction with the medical specialty boards, that all of the specialty boards' certification processes will meet the new requirements of the final rule and that the boards' certification processes will subsequently be recognized by the NRC or an Agreement State. Recognition of the specialty boards' certification processes will maintain board certification as a viable pathway and allow the licensees to avoid the burden to prepare and submit a large number of additional license amendments each year which the NRC and Agreement States would have to review and approve.

The regulations add a requirement that licensees submit preceptor statements to the Commission or an Agreement State for each individual being permitted to work as an RSO, AMP, ANP, or AU using the certification pathway. The regulations also specify separate T&E requirements for new types of use, therefore under this option, the concerns regarding the radiation safety for new types of use will 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 individuals permitted to work as RSOs, AMPs, ANPs, and AUs.

The NRC will list on its web site, rather than in its regulations, those boards whose certification processes have been recognized by the NRC or an Agreement State. This approach has the advantage of avoiding the need to go through a rulemaking to list or delist a recognized board in the regulations, increasing NRC efficiency and effective use of NRC resources.

VALUES AND IMPACTS OF THE RULEMAKING

The following is a section-by-section discussion of current regulations, changes to the regulations, and the estimated values and impacts of the rulemaking.

Definitions (§ 35.2).

Existing Regulations

Section 35.2 defines various terms.

Authorized user means a physician, dentist, or podiatrist who --

(1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or

Preceptor means 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.

Radiation Safety Officer means an individual who --

(1) Meets the requirements in §§ 35.50(a) and 35.59; or

Final Rule Changes

In § 35.2, the definition of Authorized user (AU) is changed to include individuals who qualify as AUs by meeting requirements in paragraphs (a) and (b) of new § 36.396. The definition of Preceptor is changed from “Preceptor means an individual who provides, or directs the training and experience . . ..” to read “Preceptor means an individual who provides, directs, or verifies training and experience . . ..” This definition is also changed to include individuals who qualify as AUs by meeting requirements in paragraphs (a) and (b) of new § 36.396.

Cost Impacts:

No cost impacts are expected to be associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

Information collection requirements: OMB approval (§ 35.8).

Existing Regulations

Section 35.8(b) enumerates sections for which information collection requirements, contained in Part 35, have been approved by the Office of Management and Budget.

Final Rule Changes

The final rule, in § 35.8(b) adds § 35.396 to the list of enumerated sections for which information collection requirements, contained in Part 35, have been approved by the Office of Management and Budget.

Cost Impacts:

No cost impacts are expected to be associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

Implementation (§ 35.10).

Existing Regulations

Section 35.10(b) specifies that a licensee shall implement the training requirements in §§ 35.50(a), 35.51(a), 35.55(a), 35.59, 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a) on or before October 25, 2004.

Final Rule Changes

Section 35.10(b) provides additional time for implementation of changes to regulations by amending requirements for implementation by October 24, 2005 for §§ 35.50(a) and (e), 35.51(a) and (c), 35.55(a) and (b)(1)(i), 35.59, 35.190(a) and (c)(1), 35.290(a) and (c)(1), 35.390(a) and (b)(1), 35.392(a), 35.394(a), 35.396(b) and (c), 35.490(a), 35.590(a), and 35.690(a) and (c), and for the requirement, in § 35.14(a), to provide a copy of written attestations to the Commission.

Cost Impacts:

No cost impacts are expected to be associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

License amendments (§ 35.13).

Existing Regulations

Section 35.13 specifies the circumstances under which a licensee must apply for and receive a license amendment before performing specified activities.

Section 35.13(b) requires a licensee to obtain a license amendment before it permits anyone to work as an AMP, ANP, or AU under the license, unless

-- Under § 35.13(b)(1) the individual is certified by a medical specialty board recognized by the NRC or an Agreement State and meets the § 35.59 requirements for recentness of training.

-- Under § 35.13(b)(2) the individual is certified by a medical specialty board recognized by the NRC or an Agreement State and meets the § 35.59 requirements for recentness of training.

-- Under § 35.13(b)(3) the individual is certified by a medical specialty board recognized by the NRC or an Agreement State and meets the § 35.59 requirements for recentness of training.

-- Under § 35.13(b)(4) the individual is identified as an AMP, ANP, or AU on either a Commission or Agreement State license or other equivalent permit or license recognized by NRC that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy, on a permit issued by a Commission or Agreement State specific license of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy, on a permit issued by a Commission master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy, or by a commercial nuclear pharmacy that has been authorized to identify ANPs.

Final Rule Changes

The final rule, in §§ 35.13(b)(1), 35.13(b)(2), and 35.13(b)(3), specifies a requirement for individuals, allowed by a licensee to work as AMPS, ANPs, and AUs, to have obtained a written attestation, signed by a preceptor (preceptor statement), in addition to the existing requirement of being certified by a specialty board recognized by the NRC or an Agreement State. This change is required because the final rule separates the requirement for obtaining a preceptor statement from the requirements for recognition of specialty board certifications.

The final rule, in §§ 35.13(b)(1) and 35.13(b)(3), includes a requirement for an individual seeking authorization as an AMP or an AU under § 35.690 to have training specific to the type of use for which authorization is sought.

Cost Impacts:

No cost impacts are expected to be associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

Notifications (§ 35.14).

Existing Regulations

Section 35.14 specifies the notification requirements for licensees authorized in the medical use of byproduct material.

Section 35.14(a) provides that the licensee shall provide the Commission a copy of the board certification, the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, or the permit issued by a Commission master material license broad scope permittee for each individual no later than 30 days after the date that the licensee permits the individual to work as an AMP, ANP, or AU.

Final Rule Changes

The final rule adds a requirement for licensees to provide the Commission or an Agreement State a copy of the written attestation, signed by a preceptor (preceptor statement), for each individual permitted to work as an AMP, ANP, or AU through the certification pathway. It does not change the existing requirement in § 35.12 for licensees to provide the Commission or an Agreement State with a copy of the preceptor statement for individuals being permitted to work through the alternate pathway.

Cost Impacts:

No cost impacts are expected to be associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

Training for Radiation Safety Officer (§ 35.50).

Existing Regulations

Section 35.50 specifies the T&E requirements for a Radiation Safety Officer (RSO).

Section 35.50(a) provides that the licensee shall require an individual fulfilling the responsibilities of the RSO to be certified by a specialty board whose certification process includes all of the requirements in § 35.50(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, under § 35.50(b) the individual is required to have completed: (1) a structured educational program consisting of 200 hours of didactic training in specified areas; and (2) one year of full-time radiation safety experience under the supervision of an individual identified as the RSO on a Commission or Agreement State license that authorizes similar type(s) of use of byproduct material involving specified experience.

The individual must also obtain a written certification, signed by a preceptor RSO (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee. The requirement for a preceptor statement also applies to the board certification pathway.

Alternatively, under § 35.50(c), the individual is required to be an AMP, ANP, or AU identified on the licensee's license and to have experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has RSO responsibilities.

Final Rule Changes

The final rule removes the requirement that the board certification process includes all of the T&E requirements in § 35.50(b). Under the final rule, specialty boards will no longer be required to require individuals to obtain preceptor statements as part of the board certification process. The final rule also establishes a number of less prescriptive T&E requirements for the board certification process and adds a requirement for a board-administered examination to the certification pathway.

The changes to § 35.50(c)(1) will allow a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.51(a) to serve as an RSO. The addition of § 35.50(a)(2) will allow other medical physicists to serve as RSOs.

The final rule also adds a requirement to the T&E requirements in § 35.50(e) for training in radiation safety, regulatory issues, and emergency procedures for the types of uses for which the licensee seeks approval. The term “classroom and laboratory training” is substituted for the word “didactic training” to be consistent with usage in other sections. The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.50(e).

Cost Impacts:

The NRC estimates that approximately 190 individuals will meet the T&E requirements to become RSOs under § 35.50 annually. Of these, 10 percent, or approximately 19 individuals, will meet the T&E requirements to become RSOs under § 35.50(b); 9 percent, or approximately 17 individuals, will meet the T&E requirements through certification by the specialty board currently recognized by the NRC or an Agreement State under Subparts D through H of 10

CFR Part 35; and the remaining 81 percent, or 154 individuals, will meet the T&E requirements through certification by specialty boards that are recognized by the NRC or an Agreement State.[1]

The requirements for the certification pathway will provide more flexibility than the current requirements. The educational requirement, which is focused on a scientific or engineering degree from an accredited college or university with a minimum of 20 credits in physical sciences, is much broader than the current, more prescriptive educational requirement. The experience requirement of 5 or more years of appropriate professional experience including 3 years in applied health physics (graduate training may be substituted for up to 2 years of experience) is also more flexible than current experience requirements.

The NRC anticipates cost savings for the NRC and Agreement States from the changes to § 35.50 because the final rule allows more specialty boards to be recognized by the NRC or an Agreement State which will reduce the length of the review that the NRC and Agreement States will need to perform before approving license amendments.

Assumptions:

NRC/Agreement States

Total annual amendments reviewed (35 NRC, 119 Agreement States[2])	154
Reduction in NRC/Agreement States amendment review time, hours:	3[3]

[1]These estimates, and similar estimates for other sections of 10 CFR Part 35, are taken from estimates in the regulatory analysis for the revision of 10 CFR Part 35 published as a final rule on April 24, 2002 conditioned by the NRC staff's estimate of the percentage of individuals being certified by the one specialty board currently recognized under Subparts D through H of 10 CFR Part 35.

[2]In the Final Supporting Statement for NRC Form 313, Application for Material License and NRC From 313A, Training and Experience and Preceptor Statement, the NRC staff estimates that there are approximately 3.4 times the number of Agreement State licensees as there are NRC licensees. That estimate is applied throughout this analysis.

[3]Based on the difference between an estimated 4 hours to review a complete license amendment and estimated 1 hour to review only the preceptor statement and documentation of any specific type of use training. This estimate is applied throughout this analysis.

NRC/Agreement States hourly rate:	$77
Total annual cost savings to NRC and Agreement States	$36,000
Total annual cost savings from changes to § 35.50	$36,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

Training for authorized medical physicist (§ 35.51).

Existing Regulations

Section 35.51 specifies the training requirements and experience (T&E) for an AMP.

Section 35.51(a) provides that the licensee shall require the AMP to be an individual who is certified by a specialty board whose certification process includes all of the T&E requirements in § 35.51(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.51(b) specifies T&E requirements that may be met in lieu of certification by one of the recognized specialty boards. It currently requires holding a master's or doctor's degree in one of four areas. In addition, 1 year of full-time training in therapeutic radiological physics followed by 1 year of full-time work experience under appropriate supervision at a medical institution that includes performing specified tasks is required.

Section 35.51(b) also contains a requirement that the medical physicist must obtain written certification, signed by a preceptor AMP (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an AMP. The requirement for a preceptor statement also applies to the board certification pathway.

Final Rule Changes

The final rule removes the requirement that the certification pathway includes all of the T&E requirements in § 35.51(b). Under the final rule, specialty boards will no longer be required to require individuals to obtain preceptor statements as part of the board certification process. The final rule will also establish a number of less prescriptive T&E requirements for the board certification process and will add a requirement for a board-administered examination to the certification pathway.

The final rule also adds a requirement to the T&E requirements in § 35.51(d) that requires training in the type of use for which an individual seeks authorization. The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.51(b)(2).

Cost Impacts:

The NRC estimates that approximately 100 medical physicists will meet the T&E requirements to become AMPs under § 35.51 or equivalent Agreement State regulations annually. Of these, 10 percent, or 10 medical physicists, will meet the T&E requirements to become AMPs under § 35.51(b) and the remaining 90 percent, or 90 medical physicists, will meet the T&E requirements through certification by specialty boards that are recognized by the NRC or an Agreement State under the less prescriptive requirements of the final rule.

The new requirements for the certification pathway provide more flexibility than the current requirements. The educational requirement, a masters or doctoral degree in physics, medical physics, or scientific, applied mathematics, or engineering from an accredited college or

university, is broader than the current, more prescriptive educational requirement. The experience requirement, 2 or more years of appropriate full-time training and/or supervised experience in medical physics, is also more flexible than current experience requirements.

The NRC anticipates cost savings for licensees, the NRC, and Agreement States from the changes to § 35.51 because the final rule will allow more specialty boards to be recognized by the NRC or an Agreement State which will reduce the need for licensees to apply for and receive license amendments.

Assumptions:

Licensees

Total annual amendments avoided (20 NRC, 70 Agreement States)	90
Physician/management amendment preparation time, hours:	1
Physician/management hourly rate	$100
Technical staff amendment preparation time, hours:	4
Technical staff hourly rate:	$30
Total annual cost savings to licensees	$20,000

NRC/Agreement States

Total annual amendments avoided (20 NRC, 70 Agreement States)	90
Reduction in NRC/Agreement States amendment review time, hours:	3
NRC/Agreement States hourly rate:	$77
Total annual cost savings to NRC and Agreement States	$21,000
Total annual cost savings from changes to § 35.51	$41,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

Training for an authorized nuclear pharmacist (§ 35.55).

Existing Regulations

Section 35.55 specifies the requirements for an ANP.

Section 35.55(a) provides that the licensee shall require an ANP to be certified by a specialty board whose certification process includes all of the requirements in § 35.55(b), and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.55(b) requires the pharmacist to have completed 700 hours in a structured educational program consisting of both training in specified subjects and supervised practical experience in a nuclear pharmacy performing specified tasks.

Section 35.55(b) also requires the pharmacist to have obtained written certification , signed by a preceptor ANP (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an ANP. The requirement for a preceptor statement also applies to the board certification pathway.

Final Rule Changes.

The final rule removes the requirement that the certification pathway includes all of the T&E requirements in § 35.55(b). Under the final rule, specialty boards are no longer required to require individuals to obtain preceptor statements as part of the board certification process. The final rule establishes a number of less prescriptive T&E requirements for the board certification process and adds a requirement for a board-administered examination to the certification pathway. The requirement for didactic training in paragraph (b) (1) (i) is changed to

specify that 200 hours of the 700 hours of training required under paragraph (b) (1) must be classroom and laboratory training; the term “classroom and laboratory training” is substituted for the term “didactic training” to be consistent with usage in other sections. The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.55(b)(2).

Cost Impacts:

The NRC estimates that approximately 20 pharmacists will meet the T&E requirements to become ANPs under § 35.55 or equivalent Agreement State regulations annually. Of these, 10 percent, or 2 pharmacists, will meet the T&E requirements under § 35.55(b) and the remaining 90 percent, or 18 pharmacists, will meet the T&E requirements through certification by specialty boards that are recognized by the NRC or an Agreement State under the less prescriptive requirements of the final rule.

The new requirements for the certification pathway provide more flexibility than the current requirements. The educational requirement, graduation from a pharmacy program accredited by the American Council on Pharmaceutical Education, or passing the Foreign Pharmacy Graduate Examination Committee examination, is much broader than the current, more prescriptive educational requirement. The experience requirement, 4000 hours (academic training may be substituted for some of this), is also more flexible than current experience requirements.

The NRC anticipates cost savings for licensees, the NRC, and Agreement States from the changes to § 35.55 because the final rule allows more specialty boards to be recognized by the NRC or an Agreement State which will reduce the need for licensees to apply for and receive license amendments.

Assumptions:

Licensees

Total annual amendments avoided (4 NRC, 14 Agreement States)	18
Physician/management amendment preparation time, hours:	1

Physician/management hourly rate	$100
Technical staff amendment preparation time, hours:	4
Technical staff hourly rate:	$30
Total annual cost savings to licensees	$4,000

NRC/Agreement States

Total annual amendments avoided (4 NRC, 14 Agreement States)	18
Reduction to NRC/Agreement States amendment review time, hours:	3
NRC/Agreement States hourly rate:	$77
Total annual cost savings to NRC and Agreement States	$4,000
Total annual cost savings from changes to § 35.55	$8,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

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

Existing Regulations

Section 35.190 specifies the T&E requirements for an AU of a radiopharmaceutical for uptake, dilution, and excretion studies.

Section 35.190(a) provides that the licensee shall require the AU of unsealed byproduct material for uptake, dilution, and excretion studies to be a physician who is certified by a specialty board whose certification process includes all of the requirements in § 35.190(c) and whose certification has been recognized by the Commission or an Agreement State.

Section 35.190(b) permits individuals to work as AUs for uses under § 35.100 if they are authorized under §§ 35.290, 35.390, or equivalent Agreement State requirements.

Under § 35.190(c), the physician must have completed 60 hours of T&E in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies, including classroom and laboratory training in specified areas and must have work experience under the supervision of an AU who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements in specified areas.

Section 35.190(c) also requires the physician to have obtained written certification , signed by a preceptor AU who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an AU for the medical uses authorized under § 35.100. The requirement for a preceptor statement also applies to the board certification pathway.

Final Rule Changes

Under the final rule, specialty boards will no longer be required to require individuals to obtain preceptor statements as part of the board certification process. The final rule also adds a requirement for a board-administered examination to the certification pathway. A minimum of 8 hours of didactic training is added to the requirement for classroom and laboratory training in § 35.190(c)(1). The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.190(b)(2).

Cost Impacts:

The NRC estimates that approximately 110 physicians will meet the T&E requirements to become AUs under § 35.190 or equivalent Agreement State regulations annually. Of these, 10 percent, or 11 physicians, will meet the T&E requirements to become AUs under § 35.190(c); 9 percent, or 10 physicians, will meet the T&E requirements through certification by the specialty board currently recognized by the NRC or an Agreement State under Subparts D through H of 10 CFR Part 35; and the remaining 81 percent, or 89 physicians, will meet the T&E requirements through certification by specialty boards that are recognized by the NRC or an Agreement State under the less prescriptive requirements of the final rule.

This more flexible approach should result in a more efficient process for qualified applicants to become certified by the appropriate board. It should also make the process of recognition of specialty boards by the NRC and the Agreement States more efficient.

The NRC anticipates cost savings for licensees, the NRC, and Agreement States from the changes to § 35.190 because the final rule allows more specialty boards to be recognized by the NRC or an Agreement State which will reduce the need for licensees to apply for and receive license amendments.

Assumptions:

Licensees

Total annual amendments avoided (20 NRC, 69 Agreement States)	89
Physician/management amendment preparation time, hours:	1
Physician/management hourly rate	$100
Technical staff amendment preparation time, hours:	4
Technical staff hourly rate:	$30
Total annual cost savings to licensees	$20,000

NRC/Agreement States

Total annual amendments avoided (20 NRC, 69 Agreement States)	89
Reduction to NRC/Agreement States amendment review time, hours:	3

NRC/Agreement States hourly rate:	$77
Total annual cost savings to NRC and Agreement States	$21,000
Total annual cost savings from changes to § 35.190	$41,000

Health and Safety Impacts:

None anticipated.

Benefits:

Authorized users will have T&E commensurate with risk and focused on radiation safety. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required (§ 35.200).

Existing Regulations

Section 35.200 specifies requirements for use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

Section 35.200(a) allows such use if byproduct material is obtained from a manufacturer or a preparer licensed under § 32.72.

Section 35.200(b) allows such use if byproduct material is prepared by an authorized nuclear pharmacist, a physician who is an authorized user who meets the requirements in §§ 35.290, 35.390, or, before October 24, 2005, § 35.920; or an individual under the supervision of an authorized nuclear pharmacist or authorized user as provided in § 35.200(b)(1) and (2).

Sections 35.200(c) and (d) provide additional conditions for use of unsealed byproduct material used for research.

Final Rule Changes

The final rule will make minor word changes to the requirements in § 35.200(b)(2).

Cost Impacts:

No significant cost impacts are expected to be associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

Training for imaging and localization studies (§ 35.290).

Existing Regulations

Section 35.290 specifies the T&E requirements for an AU of radiopharmaceuticals and generators for imaging and localization studies.

Section 35.290 (a) provides that the licensee shall require the AU to be a physician who is certified by a specialty board whose certification process includes all of the requirements in § 35.290(c) and whose certification has been recognized by the Commission or an Agreement State.

Section 35.290(b) acknowledges physicians who are AUs under § 35.390 or equivalent Agreement State requirements as meeting the requirements of § 35.290.

Under § 35.290(c), the physician must have completed 700 hours of T&E in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The T&E must include classroom and laboratory training in specified areas and work experience, under the supervision of an AU who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, involving specified activities.

Section 35.290(c) also requires the physician to have obtained written certification, signed by a preceptor AU who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an AU for the medical uses §§ 35.100 and 35.200. The requirement for a preceptor statement also applies to the board certification pathway.

Final Rule Changes

Under the final rule, specialty boards will no longer be required to require individuals to obtain preceptor statements as part of the board certification process. The final rule also adds a requirement for a board-administered examination to the certification pathway. A minimum of 80 hours is established for the requirement for classroom and laboratory training in § 35.290(c)(1). The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.290(b)(2).

Cost Impacts:

The NRC assumes that physicians meeting the T&E requirements to be authorized under § 35.190 will also meet the T&E requirements to be authorized under § 35.290 and therefore anticipates no significant additional costs associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

Training for use of unsealed byproduct material for which a written directive is required (§ 35.390).

Existing Regulations

Section 35.390 specifies the T&E requirements for medical use by an AU of unsealed byproduct material for which a written directive is required.

Section 35.390(a) provides that except as provided in § 35.57, the licensee shall require an AU of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.390(b) and whose certification has been recognized by the Commission or an Agreement State.

Section 35.390(b) specifies T&E requirements that may be met in lieu of certification by one of the four recognized specialty boards. It currently requires 80 hours of classroom and laboratory training in specified subjects. In addition, it requires supervised clinical experience, including use of I-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals and use of I-131 for treatment of thyroid carcinoma in three individuals.

Alternatively, the licensee shall require an AU to have completed the T&E specified in § 35.390(b) and to have obtained written certification, signed by a preceptor AU meeting certain specified requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function

independently as an AU for medical uses authorized under § 35.300. The requirement for a preceptor statement also applies to the board certification pathway.

Section 35.390(b)(1) requires completion of 700 hours of T&E in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. It specifies the topics in which classroom and laboratory training must occur and the areas in which work experience, under the supervision of an AU meeting specified requirements, must occur. Section 35.390(b)(1)(ii)(G) specifies that experience must include administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the categories for which the individual is requesting AU status, and lists four categories of administration in §§ 35.390(b)(1)(ii)(G)(1) through (G)(4).

Final Rule Changes

The final rule removes the requirement that the certification pathway includes all of the T&E requirements in § 35.390(b). Under the final rule, specialty boards are no longer required to require individuals to obtain preceptor statements as part of the board certification process. Specialty boards are no longer required to include the requirements in section 35.390(b)(1)(ii)(G) in their requirements for certification but is retained in requirements for T&E of individuals to qualify under § 35.390. The final rule also establishes a number of less prescriptive T&E requirements for the board certification process and will also add a requirement for a board-administered examination to the certification pathway. A minimum of 200 hours is established for the requirement for classroom and laboratory training in § 35.290(c)(1). The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.390(b)(2).

Cost Impacts:

The NRC estimates that approximately 100 physicians will meet the T&E requirements to become AUs under § 35.390 or equivalent Agreement State regulations annually. Of these, 5 percent, or 5 physicians, will meet the T&E requirements to become AUs under § 35.390(b)and the remaining 95 percent, or 95 physicians, will meet the T&E requirements through certification

by specialty boards that are recognized by the NRC or an Agreement State under the less prescriptive requirements of the final rule.

The NRC anticipates cost savings for licensees, the NRC, and Agreement States from the changes to § 35.390 because the final rule will allow more specialty boards to be recognized by the NRC or an Agreement State which will reduce the need for licensees to apply for and receive license amendments.

Assumptions:

Licensees

Total annual amendments avoided (22 NRC, 73 Agreement States)	95
Physician/management amendment preparation time, hours:	1
Physician/management hourly rate	$100
Technical staff amendment preparation time, hours:	4
Technical staff hourly rate:	$30
Total annual cost savings to licensees	$21,000

NRC/Agreement States

Total annual amendments avoided (22 NRC, 73 Agreement States)	95
Reduction to NRC/Agreement States amendment review time, hours:	3
NRC/Agreement States hourly rate:	$77
Total annual cost savings to NRC and Agreement States	$22,000
Total annual cost savings from changes to § 35.390	$43,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

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) (§ 35.392).

Existing Regulations

Section 35.392 specifies the T&E requirements for an AU 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).

Section 35.392(a) provides that, except as provided in § 35.57, the licensee shall require an AU, for the oral administration of sodium iodide I-131 requiring a written directive for quantities less than or equal to 1.22 gigabecquerels (33 millicuries), to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.392(c) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.392(b) provides that the licensee shall require an AU to be an AU under §§ 35.390(a), 35.390(b), for uses listed in §§ 35.390(b)(1)(ii)(G)(1) or (2), or 35.394 or equivalent Agreement State requirements.

Alternatively, § 35.392(c) provides that the licensee shall require an AU to have successfully completed 80 hours of classroom and laboratory training in specified subjects and to have work experience under the supervision of an AU who meets specified requirements involving specified activities, including administering dosages to patients or human research subjects that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131.

Section 35.392(c) also requires the physician to have obtained written certification , signed by a preceptor AU who meets specified requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an AU for medical uses authorized under § 35.300. The requirement for a preceptor statement also applies to the board certification pathway.

Final Rule Changes

The final rule makes minor word changes to the requirements. The final rule modifies the criteria for approval of board certifications. Under the final rule, specialty boards are no longer required to require individuals to obtain preceptor statements as part of the board certification process. The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.392(c)(3).

Cost Impacts:

The NRC estimates that approximately 100 physicians will meet the T&E requirements to become AUs under § 35.392 or equivalent Agreement State regulations annually. Of these, 10 percent, or 10 physicians, will meet the T&E requirements to become AUs under § 35.392(b) and the remaining 90 percent, or 90 physicians, will meet the T&E requirements through certification by specialty boards that are recognized by the NRC or an Agreement State under the less prescriptive requirements of the final rule.

The NRC anticipates cost savings for licensees, the NRC, and Agreement States from the changes to § 35.392 because the final rule will allow more specialty boards to be recognized by the NRC or an Agreement State which will reduce the need for licensees to apply for and receive license amendments.

Assumptions:

Licensees

Total annual amendments avoided (20 NRC, 70 Agreement States)	90
Physician/management amendment preparation time, hours:	1

Physician/management hourly rate	$100
Technical staff amendment preparation time, hours:	4
Technical staff hourly rate:	$30
Total annual cost savings to licensees	$20,000

NRC/Agreement States

Total annual amendments avoided (20 NRC, 70 Agreement States)	90
Reduction in NRC/Agreement States amendment review time, hours:	3
NRC/Agreement States hourly rate:	$77
Total annual cost savings to NRC and Agreement States	$21,000
Total annual cost savings from changes to § 35.392	$41,000

Health and Safety Impacts:

None anticipated.

Benefits:

Clarifies regulations. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

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

Existing Regulations

Section 35.394 specifies the T&E requirements for an AU for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).

Section 35.394(a) provides that, except as provided in § 35.57, the licensee shall require an AU, for the oral administration of sodium iodide I-131 requiring a written directive for quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.394(c) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.394(b) provides that the licensee shall require an AU to be an AU under § 35.390(a), § 35.390(b) for uses listed in § 35.390(b)(1)(ii)(G)(2), or equivalent Agreement State requirements.

Alternatively, § 35.394(c) provides that the licensee shall require an AU to have successfully completed 80 hours of classroom and laboratory training in specified subjects and to have work experience under the supervision of an AU who meets specified requirements involving specified activities, including administering dosages to patients or human research subjects that includes at least three cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131.

Section 35.394(c) also requires the physician to have obtained written certification , signed by a preceptor AU who meets specified requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an AU for medical uses authorized under § 35.300. The requirement for a preceptor statement also applies to the board certification pathway.

Final Rule Changes

The final rule makes minor word changes to the requirements. The final rule modifies the criteria for approval of board certifications. Under the final rule, specialty boards will no longer be required to require individuals to obtain preceptor statements as part of the board certification process. The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.394(c)(3).

Cost Impacts:

The NRC assumes that physicians meeting the T&E requirements to be authorized under § 35.394 are included in the total under§ 35.392 and therefore anticipates no significant additional costs associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Clarifies regulations. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

Training for the parenteral administration of unsealed byproduct material requiring a written directive (§ 35.396).

Existing Regulations
Section 35.390 specifies the T&E requirements for medical use by an AU of unsealed byproduct material for which a written directive is required.

Section 35.390(a) provides that except as provided in § 35.57, the licensee shall require an AU of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.390(b) and whose certification has been recognized by the Commission or an Agreement State.

Section 35.390(b) specifies T&E requirements that may be met in lieu of certification by one of the four recognized specialty boards. It currently requires 80 hours of classroom and laboratory training in specified subjects. In addition, it requires supervised clinical experience, including use of I-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals and use of I-131 for treatment of thyroid carcinoma in three individuals.

Alternatively, the licensee shall require an AU to have completed the T&E specified in § 35.390(b) and to have obtained written certification, signed by a preceptor AU meeting certain specified requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an AU for medical uses authorized under § 35.300. The requirement for a preceptor statement also applies to the board certification pathway.

Section 35.390(b)(1) requires completion of 700 hours of T&E in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. It specifies the topics in which classroom and laboratory training must occur and the areas in which work experience, under the supervision of an AU meeting specified requirements, must occur. Section 35.390(b)(1)(ii)(G) specifies that experience must include administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the categories for which the individual is requesting AU status, and lists four categories of administration in §§ 35.390(b)(1)(ii)(G)(1) through (G)(4).

Final Rule Changes

The final rule creates a new § 35.396 which establishes requirements for T&E for parenteral administration of byproduct material for which a written directive is required. This section was created in response to public comments on the proposed rule that indicated that a certain class of physicians, who now perform these procedures, would not meet the criteria in the current or in the proposed § 35.390. As for other sections in Subpart E, specialty boards will not be required to require individuals to obtain preceptor statements as part of the board certification process. The final rule provides a pathway for becoming a AU for uses of byproduct material under § 35.300, for individuals who may have acquired adequate T&E other than those specified in §§ 35.390 and other sections of Subpart E. The requirements in § 35.396 were modeled after the requirements in other sections of Subpart E and include 80 hours of T&E specific to the use of unsealed sources and experience with at least 3 cases involving parenteral administration of byproduct material for which a WD is required. § 35.396 allows for individuals to take credit for T&E associated with other medical uses of byproduct material that

may be applicable to the uses of unsealed byproduct material, e.g., individuals who are certified by boards who meet the requirements of §§ 35.490 or 35.690 for the use of sealed sources. This new section will provide the flexibility needed to allow individuals, who do not meet other requirements in Subpart E, to serve as AUs for parenteral administration of byproduct material for which a WD is required while ensuring adequacy of T&E for these uses to be safe.

Cost Impacts:

The NRC assumes that physicians meeting the T&E requirements to be authorized under § 35.396 are included in the total under § 35.390 and therefore anticipates no significant additional costs associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35 and will allow individuals who meet similar requirements in Subpart J to meet the requirements in the new rule, increasing regulatory efficiency.

Training for use of manual brachytherapy sources (§ 35.490).

Existing Regulations

Section 35.490 specifies the T&E requirements for an AU of manual brachytherapy sources.

Section 35.490(a) provides that, except as provided in § 35.57, the licensee shall require an AU of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who is certified by a medical specialty board whose certification process includes all of the

requirements in § 35.490(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.490(b) provides that the licensee shall require an AU to have: (1) completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes 200 hours of classroom and laboratory training in specified subjects; (2) 500 hours of work experience under the supervision of an AU who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution involving specified activities; and (3) obtained 3 years of supervised clinical experience in radiation oncology under an AU who meets the requirements in § 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 Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience.

Section 35.490(b) also requires the physician to have obtained written certification , signed by a preceptor AU who meets the requirements in § 35.490 or equivalent Agreement State requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an AU of manual brachytherapy sources for the medical uses authorized under § 35.400. The requirement for a preceptor statement also applies to the board certification pathway.

Final Rule Changes

The final rule removes the requirement that the certification pathway includes all of the T&E requirements in § 35.490(b). Under the final rule, specialty boards are no longer required to require individuals to obtain preceptor statements as part of the board certification process. The final rule also establishes a number of less prescriptive T&E requirements for the board certification process and adds a requirement for a board-administered examination to the certification pathway. The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.490(b)(3).

Cost Impacts:

The NRC estimates that approximately 150 physicians will meet the T&E requirements to become AUs under § 35.490 or equivalent Agreement State regulations annually. Of these, 5 percent, or 7 physicians, will meet the T&E requirements to become AUs under § 35.490(b) and the remaining 95 percent, or 143 physicians, will meet the T&E requirements through certification by specialty boards that are recognized by the NRC or an Agreement State under the less prescriptive requirements of the final rule.

The NRC anticipates cost savings for licensees, the NRC, and Agreement States from the changes to § 35.490 because the final rule will allow more specialty boards to be recognized by the NRC or an Agreement State which will reduce the need for licensees to apply for and receive license amendments.

Assumptions:

Licensees

Total annual amendments avoided (33 NRC, 110 Agreement States)	143
Physician/management amendment preparation time, hours:	1
Physician/management hourly rate	$100
Technical staff amendment preparation time, hours:	4
Technical staff hourly rate:	$30
Total annual cost savings to licensees	$31,000

NRC/Agreement States

Total annual amendments avoided (33 NRC, 110 Agreement States)	143
Reduction to NRC/Agreement States amendment review time, hours:	3
NRC/Agreement States hourly rate:	$77
Total annual cost savings to NRC and Agreement States	$33,000
Total annual cost savings from propose to § 35.490	$64,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

Training for ophthalmic use of strontium-90 (§ 35.491).

Existing Regulations

Section 35.491 specifies the T&E requirements for an AU for ophthalmic use of strontium-90.

Section 35.491(b)(3) requires that individuals obtain written certification, signed by a preceptor AU meeting certain specified requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an AU of strontium-90 for ophthalmic use.

Final Rule Changes

The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.491(b)(3).

Cost Impacts:

No significant cost impacts are expected to be associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

Training for use of sealed sources for diagnosis (§ 35.590).

Existing Regulations

Section 35.590 specifies the T&E requirements for an AU of sealed sources for diagnosis.

Section 35.590(a) provides that the licensee shall require the AU of a diagnostic sealed source for use in a device authorized under § 35.500 to be a physician, dentist, or podiatrist who is certified by a specialty board whose certification process includes all of the requirements in § 35.590(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.590(b) requires eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that include: (1) radiation physics and instrumentation; (2) radiation protection; (3) mathematics pertaining to the use and measurement of radioactivity; (4) radiation biology; and (5) training in the use of the device for the uses requested.

Final Rule Changes

The final rule will make minor word changes to the requirements.

Cost Impacts:

No significant cost impacts are expected to be associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.690).

Existing Regulations

Section 35.690 specifies the T&E requirements for the AU of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Section 35.690(a) requires that, except as provided in § 35.57, the licensee shall require the AU of a sealed source for a use listed in § 35.600 to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.690(b) and whose certification has been recognized by the Commission or by an Agreement State.

Alternatively, § 35.690(b) provides that the physician must have completed a structured educational program in basic radionuclide techniques, including specified areas of training, applicable to the use of a sealed source in a therapeutic medical unit and must have completed 200 hours of classroom and laboratory training in specified topics and 500 hours of work experience, including specified activities, under the supervision of an AU who meets the requirements in § 35.690 or equivalent Agreement State requirements at a medical institution; and has completed 3 years of supervised clinical experience in radiation oncology, under an AU who meets the requirements in § 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 the Committee on

Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience.

Section 35.690(b) also requires the physician to have obtained written certification, signed by a preceptor AU, who meets the requirements in § 35.690 or equivalent Agreement State requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an AU of each type of therapeutic medical unit for which the individual is requesting AU status. The requirement for a preceptor statement also applies to the board certification pathway.

Final Rule Changes

The final rule removes the requirement that the certification pathway includes all of the T&E requirements in § 35.690(b). Under the final rule, specialty boards are no longer be required to require individuals to obtain preceptor statements as part of the board certification process. The final rule also establishes a number of less prescriptive T&E requirements for the board certification process and adds a requirement for a board-administered examination to the certification pathway.

The final rule also adds a requirement to the T&E requirements in § 35.690(d) that requires training in device operation, safety procedures and clinical use for the types of units for which an individual seeks authorization. The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.690(b)(3).

Cost Impacts:

The NRC estimates that approximately 150 physicians will meet the T&E requirements to become AUs under § 35.690 or equivalent Agreement State regulations annually. Of these, 5 percent, or 7 physicians, will meet the T&E requirements to become AUs under § 35.690(b) and the remaining 95 percent, or 143 physicians, will meet the T&E requirements through certification by specialty boards that are recognized by the NRC or an Agreement State under the less prescriptive requirements of the final rule.

The NRC anticipates cost savings for licensees, the NRC, and Agreement States from the changes to § 35.690 because the final rule will allow more specialty boards to be recognized by the NRC or an Agreement State which will reduce the need for licensees to apply for and receive license amendments.

Assumptions:

Licensees

Total annual amendments avoided (33 NRC, 110 Agreement States)	143
Physician/management amendment preparation time, hours:	1
Physician/management hourly rate	$100
Technical staff amendment preparation time, hours:	4
Technical staff hourly rate:	$30
Total annual cost savings to licensees	$31,000

NRC/Agreement States

Total annual amendments avoided (33 NRC, 110 Agreement States)	143
Reduction to NRC/Agreement States amendment review time, hours:	3
NRC/Agreement States hourly rate:	$77
Total annual cost savings to NRC and Agreement States	$33,000
Total annual cost savings from changes to § 35.690	$64,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

SUMMARY OF COST IMPACTS ON LICENSEES

The impacts of the final rule should result in some savings from the change to less prescriptive and more flexible requirements for the certification pathway. Individuals are allowed significantly more flexibility in becoming approved through the certification pathway. It is not possible to fully quantify estimates of cost impacts. However, the net result should be cost savings to licensees and individuals exceeding the $147,000 annual savings from the changes to the T&E requirements in 10 CFR Part 35.

SUMMARY OF COST IMPACTS ON THE NRC AND AGREEMENT STATES

Costs consist of the NRC/Agreement State staff time needed to assess the boards' certification processes, and NRC costs to develop the rulemaking. Also, the NRC and Agreement States should experience annual cost savings from the reduced length of time to review license amendments for RSOs and the avoidance of the need for license amendments for AMPs, ANPs, and AUs of approximately $191,000.

Costs of Assessing Board Certification Processes: The cost of assessing specialty boards' certification processes for the purpose of NRC recognition should not change significantly, but any change should result in somewhat lower costs as board requirements are less prescriptive.

Rulemaking Costs: The costs of developing a proposed and final rule to amend T&E requirements in 10 CFR Part 35 are NRC staff time needed. It is estimated that 0.9 full-time equivalent staff years (FTEs) will be required to develop a proposed and final rule. At NRC labor rates of $137K per year, 0.9 FTEs is $123K.

PREFERRED ALTERNATIVE AND DECISION RATIONALE

The preferred alternative is to implement a rulemaking to amend requirements for T&E in 10 CFR Part 35.

The action is in keeping with a more performance-based, less prescriptive 10 CFR Part 35. This action should enhance regulatory efficiency by bringing NRC regulations more in accordance with the certification procedures of the medical specialty boards. The medical specialty boards provide a valuable service by maintaining a pathway for applicants to obtain AU status under NRC regulations. It is beneficial for the NRC to maintain the certification pathway.

It is not possible to fully estimate quantitative cost savings from this action. However, maintaining the certification pathway should result in cost savings in excess of the $338,000 resulting from the changes to the T&E requirements in 10 CFR Part 35. Also, more flexible, less prescriptive T&E requirements for the certification pathway should result in savings to applicants.

While cost savings to individuals may not be substantial, total cost savings for all applicants using the certification pathway could be substantial. The total number of applicants for all types of use covered by the final rule change is estimated at approximately 820 annually[4]. Even assuming individual cost savings for each applicant were small, annual total savings could be substantial. Compared to the cost of the action, an estimated $123,000, the quantitative net benefits of the final rule alone are positive.

IMPLEMENTATION

The NRC listing of recognized specialty boards will be on the NRC's web site, rather than in the regulations. NRC will update the list of recognized boards in a timely manner.

Schedule

The NRC final rule becomes effective 30 days after publication in the Federal Register. Requirements in Subpart J will remain in effect for an additional year beyond the 2-year transition period for Subpart J, that is, until October 24, 2005. The action is being effected by a

[4]Based on total of all estimated annual applicants under the certification pathway, for each section of 10 CFR Part 35 being changed by the final rule.

separate rulemaking (69 FR 55736, September 16, 2004)). This is an additional year beyond that assumed when cost estimates were prepared for the proposed rule. Difference in estimated costs due to this difference in time are negligibly small.

24722

Submission of Federal Rules Under the Congressional Review Act

☑ **President of the Senate** ☐ **Speaker of the House of Representatives** ☐ **GAO**

Please fill the circles electronically or with black pen or #2 pencil.

1. Name of Department or Agency
U.S. Nuclear Regulatory Commission

2. Subdivision or Office
Nuclear Material Safety and Safeguards

3. Rule Title
Final Rule - 10 CFR Part 35, "Medical Use of Byproduct Material"

4. Regulation Identifier Number (RIN) or Other Unique Identifier (if applicable)
RIN 3150-AH19

5. Major Rule ○ Non-major Rule ◉

6. Final Rule ◉ Other ○ _____

7. With respect to this rule, did your agency solicit public comments? Yes ◉ No ○ N/A ○

8. Priority of Regulation (fill in one)
◉ Economically Significant; or Significant; or Substantive, Non Significant
○ Routine and Frequent or Informational/Administrative/Other (Do not complete the other side of this form if filled in above.)

9. Effective Date (if applicable) **90 days after publication in the Federal Register**

10. Concise Summary of Rule (fill in one or both) attached ○ stated in rule ◉

Submitted by: _____ (signature)

Name: **Dennis K. Rathbun**

Title: **Director, Office of Congressional Affairs**

For Congressional Use Only:

Date Received: _____

Committee of Jurisdiction: _____

3/23/99

	Yes	No	N/A
A. With respect to this rule, did your agency prepare an analysis of costs and benefits?	◉	○	○
B. With respect to this rule, by the final rulemaking stage, did your agency			
1. certify that the rule would not have a significant economic impact on a substantial number of small entities under 5 U.S.C. § 605(b)?	◉	○	○
2. prepare a final Regulatory Flexibility Analysis under 5 U.S.C. § 604(a)?	◉	○	○
C. With respect to this rule, did your agency prepare a written statement under § 202 of the Unfunded Mandates Reform Act of 1995?	○	◉	○
D. With respect to this rule, did your agency prepare an Environmental Assessment or an Environmental Impact Statement under the National Environmental Policy Actg (NEPA)?	◉	○	○
E. Does this rule contain a collection of information requiring OMB approval under the Paperwork Reduction Act of 1995?	◉	○	○
F. Did you discuss any of the following in the preamble to the rule?	○	◉	○
• E.O. 12612, Federalism	○	○	○
• E.O. 126630, Government Actions and Interference with Constitutionally Protected Property Rights	○	○	○
• E.O. 12866, Regulatory Planning and Review	○	○	○
• E.O. 12875, Enhancing the Intergovernmental Partnership	○	○	○
• E.O. 12988, Civil Justice Reform	○	○	○
• E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks	○	○	○
• Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify) **National Technology Transfer Advancement Act of 1995 (NTTAA)**			

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