RULEMAKING ISSUE
NOTATION VOTE

August 21, 2003 SECY-03-0145

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL - RECOGNITION OF SPECIALTY BOARDS

PURPOSE:

To request Commission approval to publish a proposed rule, in the *Federal Register*, that would amend 10 CFR Part 35, "Medical Use of Byproduct Material," to modify training and experience requirements related to recognition of specialty board certifications.

SUMMARY:

This paper transmits a proposed rule to amend 10 CFR Part 35 to the Commission for consideration. The proposed rule would amend the regulation 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, authorized medical physicists, authorized nuclear pharmacists or radiation safety officers. The proposed rule would also revise the requirements for demonstrating the adequacy of training and experience for pathways other than the board

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certification pathway. A draft regulatory analysis and environmental assessment have been completed to support this rule.

BACKGROUND:

During development of proposed and final rules for Part 35 [August 13, 1998 (63 FR 43516) and April 24, 2002 (67 FR 20249), respectively], there was a general belief that the specialty boards recognized by the U.S. Nuclear Regulatory Commission (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 preceptor certification and work experience.

On February 19, 2002, the Advisory Committee on Medical Uses of Isotopes (ACMUI) briefed the Commission and expressed a concern that if the final rule, as drafted, became effective there could be a potential shortage of individuals qualified to serve as radiation safety officers (RSOs), authorized medical physicists (AMPs), authorized nuclear pharmacists (ANPs) and authorized users (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 transition period (i.e., Subpart J continues to be effective for two years for NRC licensees) during which the NRC could work to resolve the problem. 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), with an effective date of October 24, 2002. The transition period will end 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 (T&E) issue related to recognition of specialty board certifications.

The ACMUI formed a subcommittee to develop recommendations on this issue. After considering comments received during a public meeting conducted on June 21, 2002, along with letters from stakeholders, the subcommittee developed a final recommendation that the full ACMUI approved during a public tele-conference meeting, on July 8, 2002. These recommendations were submitted to the NRC on August 1, 2002. The NRC staff presented three options for addressing T&E requirements in SECY-02-0194, dated October 30, 2002, two of which included recommendations of the ACMUI. In SRM-02-0194, issued February 12, 2003 (Attachment 1), the Commission approved preparation of a proposed rule to modify the T&E requirements, based on the ACMUI's recommendations, with certain specific exceptions as discussed in more detail, below.

DISCUSSION:

In accordance with SRM-02-0194, the NRC staff has developed a proposed rule (Attachment 2), based on the ACMUI's recommendations. However, the Commission did not agree with the ACMUI's recommendations to change the preceptor statement and to list recognized boards in the rule itself. In SRM-02-0194, the Commission directed that the preceptor statement remain as written in the final rule; that the staff clarify that preceptor statement 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; and that the names of recognized boards be posted on the NRC's web site. The proposed rule was developed by a working group, formed in March 2003, which included a representative of the Organization of Agreement States (OAS) and Conference of Radiation Control Program Directors (CRCPD). On May 20, 2003, a public meeting was also held to solicit early input on the proposed rule from representatives of professional speciality boards and other interested parties.

The current regulations in 10 CFR Part 35 offer three pathways for individuals to satisfy training and experience requirements to be approved as an RSO, AMP, ANP, or AU. These pathways are: (1) approval of 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 the sake of this discussion, pathway 1 will be referred to as the "certification pathway;" pathway 2 as the "alternate pathway." Discussion of rule changes are organized according to changes in criteria for recognition of specialty boards, termed the "certification pathway," and changes dealing with the "alternate pathway" (i.e., the listings in the rule of requirements for T&E for those who do not choose the certification pathway). The principal rule changes would involve revising the criteria for the certification pathway so that the requirements are less prescriptive than those in the current rule.

The proposed rule would revise the criteria that a board must meet to be recognized by the NRC or an Agreement State. The proposed 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, obtaining a written preceptor statement, and clarifying that individuals are to have T&E related to the type of use (termed "modality" by the ACMUI) for which they would be responsible. The required degree (baccalaureate, masters, or doctorate) and the amount of professional experience varies depending on what type of approval is sought (for RSO, AMP, or an ANP). The certification pathway also includes a specification for number of hours of T&E for ANPs and AUs for uses of certain byproduct material under 10 CFR 35.100, 35.200, 35.300 (in 35.390, 35.392, 35.394, for uses under 35.300), and 35.500.

The proposed rule would provide the boards more latitude in making the determination that an individual is fully trained and capable of performing duties related to radiation safety. The NRC staff believes that the specialty boards will be able to apply to candidates the T&E criteria contained in the proposed rule. The proposed changes to the certification pathway would continue to ensure the safe use of byproduct material by medical licensees by establishing criteria for specialty boards to use in granting certification.

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

The staff did not adopt certain recommendations made by the ACMUI. The staff made changes to be consistent with NRC's approach to regulatory language and to make the regulations internally consistent. These changes have been discussed with the Chairs of the full ACMUI and ACMUI's subcommittee on T&E, during development of the proposed rule, and they agreed with

the staff's changes in these areas. The draft proposed rule was distributed to the ACMUI in June 2003, for review during the period of Agreement State review.

At a teleconference held on July 17, 2003, the full ACMUI discussed the draft proposed rule. During the teleconference, the ACMUI approved 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 paragraph § 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 § 35.390(a)(1) for uses under § 35.600. Secondly, the ACMUI recommended that the experiential requirements, 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 adopted because the NRC staff believes 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 written directive is required. Furthermore, if the requirement were removed from the certification pathway, individuals and applicants for licenses, or amendments, would be required to provide documentation of completion of requirements for experience required under § 35.390(b)(1)(ii)(G), in addition to evidence of board certification, to gain approval as AUs. Therefore, this requirement was retained in the proposed rule. Thirdly, the ACMUI recommended that the requirement for a preceptor statement be separated from the board certification pathway and the alternate pathway, and specified separately as a new paragraph in each training section. Lastly, the ACMUI recommended that the word "attest" should be used in place of certify (certification) in preceptor statements. The last two recommendations are discussed in detail below. They were not adopted because, in SRM-02-0194, the Commission stated that the preceptor statement should remain in the current regulations. Further, Agreement States who commented on the proposed rule agreed with the Commissions directive to keep the preceptor statement as written. With regard to the use of the word "attest" rather than "certify," the NRC staff believes placing this matter before all stakeholders and receiving their input is appropriate and, therefore, a question is posed in the FRN to seek stakeholder input on whether this change should be made.

Preceptor Certification

Part 35 currently requires that the preceptor who signs the certification be an RSO, AMP, ANP, or AU, as appropriate to the type of approval sought by a candidate to serve in one of these capacities. This requirement applies to both board certification and the alternate pathway. The ACMUI expressed concern that the existing preceptor statement could be viewed as a testament to clinical competence and recommended that the preceptor concept be modified to become documentation for completion of a training program.

On May 20, 2003, during an open meeting of the ACMUI, the NRC staff briefed the ACMUI on its approach to drafting the proposed rule. This briefing included a discussion of the requirement in SRM-02-0914 to retain, in the proposed rule, the preceptor statement, as written in the current Part 35. During its meeting with the Commission on May 28, 2003, the ACMUI expressed concern regarding the NRC's intent to retain requirements in Part 35 for certifications by

preceptors. As a result of this meeting, the Commission issued an SRM dated June 20, 2003 (M030528B), indicating that, as the Commission directed in a Staff Requirements Memorandum on SECY-02-0194, dated February 12, 2003, the staff, with appropriate interactions with the ACMUI, should continue its development of a proposed rule to modify the training and experience requirements in 10 CFR 35 so that the revised rule can be in place as promptly as possible. The Commission also instructed the NRC staff, in SRM-02-0194, to clarify that the preceptor language does not require an attestation of general clinical competency, but requires an attestation sufficient to demonstrate that the candidate has the knowledge to fulfill the duties of the position for which certification is sought. This clarification is included in the "Supplementary Information" for the proposed rule.

During the teleconference with ACMUI, conducted on July 17, 2003, ACMUI members continued to voice concern about having recognition of boards conditioned on requiring candidates for certification to obtain written attestation of competency signed by a preceptor. Concern was also expressed by the ACMUI about the NRC's requirements that an authorized user must sign the preceptor statement rather than a program director. During the teleconference, ACMUI proposed that, if the Commission maintained it was necessary to include a preceptor statement, that this requirement be separated ("decoupled") from the criteria for recognition of board certifications, as well as the alternative pathway. Specifically, ACMUI suggested that the requirement be set forth as a new paragraph in each "training section." This would place the responsibility upon the individual seeking authorized status to obtain a preceptor statement in addition to fulfilling the requirements for board certification (the condition currently applies for the alternate pathway). Agreement State representatives participating in the teleconference agreed with this recommendation. During the teleconference, the NRC staff agreed that if ACMUI documented its position, the staff would provide that documentation to the Commission.

In a letter dated July 23, 2003, Dr. Manuel Cerqueira, Chair of the ACMUI, advised the NRC Staff that the ACMUI had restated its consensus position that a preceptor attestation should not be a requirement for specialty boards to qualify under 10 CFR Part 35 sections. He stated further that ACMUI recommended that requirements for a preceptor statement be removed from the certification pathway; however, if the Commission still felt it necessary to include a preceptor statement for all authorized positions named in Part 35, the ACMUI recommended that this requirement be separated from the board certification pathway and from the alternate pathway and specified separately as a new paragraph in each "training section." In accordance with statements by the NRC staff made during the July 17 teleconference, this letter, containing ACMUI's recommendation, is being provided to the Commission as the ACMUI's alternative (Attachment 3). Alternate wording for appropriate sections of the FRN appears in Attachment 4 for consideration by the Commission if it adopts ACMUI's recommendation.

The ACMUI also recommended, during the teleconference, that the word "attest" should be used in place of "certify"in preceptor statements. ACMUI explained that the reason for this recommendation was that preceptors do not "certify" individuals, but "attest." This proposal has not been adopted by the staff because, in SRM -02-0194, the Commission stated that the preceptor statement should remain as currently written in the regulations. As noted above, a question on this change is posed in the FRN.

<u>Listing/De-listing of Specialty Boards</u>

All current and new boards whose certification process meets the NRC's criteria for recognition would be listed on the NRC's web site rather than in the rule. This approach has the advantage of avoiding the necessity to amend Part 35 to effect recognition each time a new board is added to the listing. The ACMUI and stakeholders participating in a public meeting on May 20, 2003, (attended primarily by specialty board representatives) agreed with this approach. The staff is developing a procedure for both the listing and de-listing of specialty boards and will discuss the draft procedure with the ACMUI at its October 2003 meeting, as well as with the OAS. The staff plans to place the procedure on the NRC web page before the effective date of the final rule.

The procedure will include a mechanism for requesting additional or clarifying information from a specialty board, criteria for de-listing a board, and steps to notify a board of the NRC's action. The staff plans to consult with the ACMUI, if needed, before a decision on recognition of a board is made and before a final decision to de-list a board is made. The procedure will also include a step for Commission notification before de-listing a board.

Authorized Medical Physicists as RSOs.

Current regulations provide, in § 35.50(c), that an AMP identified on a licensee's license can serve as an RSO. However, the 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 AUs 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. The NRC staff believes that medical physicists who are certified by a specialty board 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. Therefore, the proposed rule includes a change to the regulations in § 35.50(c) that would allow medical physicists, who are certified by a specialty board recognized by the NRC or an Agreement State, to serve as RSOs, while retaining the requirement that individuals have experience specific to the types of use for which they would be responsible. This change would remove an impediment for individuals who have adequate T&E to becoming approved as RSOs. It would also avoid placing a burden on licensees to apply for an exemption to the regulations and on NRC and Agreement State staff who would be required to process an application for an exemption to regulations in order to approve a licensee's request to have a medical physicist, certified by a recognized specialty board, serve as an RSO.

AGREEMENT STATE ISSUES:

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 proposed rule would be a matter of compatibility between NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. The proposed rule changes would all be classified as Category B. 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 person from the State of Alabama represented the OAS and participated as a member of the working group with the NRC staff in development of this proposed rule.

Agreement States must adopt the current rule, published in April 2003, by October 24, 2005, (3 years from the effective date of the rule). Adoption by Agreement States of the proposed rule under discussion in this paper is tentatively planned to coincide with the date by which they must adopt the current rule, that is, by October 24, 2005. However, this would result in a shortening of the time available to States to develop compatible T&E requirements. During the OAS meeting in October 2002, the Agreement States voiced their concern regarding the adoption of compatible T&E requirements by October 24, 2005. The staff is soliciting comments from all stakeholders on the issue of the timing of the adoption of compatible T&E requirements by Agreement States.

AGREEMENT STATE COMMENTS ON THE PROPOSED RULE:

The proposed rule was distributed for Agreement State comment, and comment letters were received from Alabama, Florida, Illinois, Maine, Washington and Wisconsin. All States voiced support for the Commission's decision to continue to require a preceptor statement as written in the current regulations. As noted above, Agreement States who participated in the tele-conference agreed with the ACMUI's recommendation to "decouple" the requirement for a preceptor statement from the requirements for recognition of board certifications. One State also indicated support for the addition of requirements for training specific to type-of-use. Three States indicated that they should have 3 years to adopt the rule. As discussed in SECY-02-0194, the NRC is soliciting input on this subject in the FRN containing the proposed rule. One State suggested that the term "high energy," used in the section of the proposed rule in which requirements for training of candidates for AMPs are discussed, should be defined. The NRC staff believes that defining the term would be overly prescriptive and might be misinterpreted. Discussion of this point was included in the supplementary information in the FRN. One State asked for clarification related to processes for keeping records of training related to specific type-of-use, suggesting that this duty be placed on specialty boards. The NRC staff believes this would impose an unnecessary burden on boards and has not incorporated this suggestion in the proposed rule. Two States expressed concern about enacting a rule which included reference to the NRC's web site as the source for listing the names of specialty boards recognized by the NRC or an Agreement State, indicating that there is a need for public involvement in their rulemaking process. The staff notes that the criteria for board recognition are contained in this proposed rulemaking and, thus, will have public involvement. The staff has only proposed that the names of these boards that meet the proposed criteria will be listed on the NRC website. The issue will also be raised with Agreement States during the OAS meeting in October, 2003. Agreement States who commented on the proposed rule agreed with the Commission's direction that attestations should be signed by an individual who is approved by the NRC or an Agreement State as an RSO, AMP, ANP or AU (for the corresponding category of approval). The NRC staff is in agreement with the rationale of the Agreement States, i.e., that these individuals are well suited to offer an independent, informed opinion about the knowledge and skills needed to fulfill the duties for which approval is sought.

COORDINATION:

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

RESOURCES:

To complete and implement the rulemaking, 0.4 full-time equivalent positions will be required. No contractual support is anticipated. These resources are included in the current budget.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication, in the *Federal Register*, the proposed amendments to Part 35 (Attachment 2).

2. Certify that, based on the information currently available, the proposed rule, if adopted, is not likely to have a significant economic impact on a substantial number of small entities.

3. Note that:

    a. The proposed amendments will be published in the *Federal Register*, allowing 75 days for public comment.

    b. 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).

    c. A draft Regulatory Analysis has been prepared for this rulemaking (Attachment 5).

    d. Appropriate Congressional committees will be informed of this action.

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

/RA/

William D. Travers
Executive Director
for Operations

Attachments:
1. SRM Dated February 12, 2003
2. Draft *Federal Register* notice
3. Letter From ACMUI Chair, Manuel D. Cerqueira, to Thomas Essig, Dated July 23, 2003

4. Alternative language for FRN
5. Draft Regulatory Analysis

February 12, 2003

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary **/RA/**

SUBJECT: STAFF REQUIREMENTS - SECY-02-0194 - OPTIONS FOR ADDRESSING PART 35 TRAINING AND EXPERIENCE ISSUES ASSOCIATED WITH RECOGNITION OF SPECIALTY BOARDS BY NRC

The Commission has approved Option 3. The staff should prepare a proposed rule, without the generation of an additional rulemaking plan, to modify the training and experience requirements based on the recommendations submitted by the Advisory Committee on the Medical Uses of Isotopes (ACMUI). The Commission has approved the proposal that all boards that meet the criteria for recognition by the NRC will be listed on the NRC website rather than in the rule itself.

In addition, the preceptor statement should remain as written in the final Part 35 rule. 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 for both pathways of certification (i.e., through board certification or through training and experience).

Because of the important role of Board certification, a clear regulatory determination that all Boards, both new and existing, meet the relevant criteria should be required. As part of the rulemaking process, the staff should discuss implementing procedures both for adding new speciality boards to the recognized listing and for removing boards from the recognized list. While the NRC staff is not expected to conduct inspections of the recognized speciality boards, the staff should monitor trends in medical events. If a particular speciality for some reason has a series of medical events that can be attributed to inadequate radiation safety training, the staff will need to determine if the training should have been site specific or should have been provided by the speciality boards. If the staff determines that changes in radiation safety training by a recognized speciality board are necessary and the speciality either cannot or will not make adequate changes to its training program to address our needs, then that speciality board should be removed from our recognized list. However, appropriate due process would require that the procedures are established in advance for removing a speciality board from the recognized list. In addition, the Commission should be informed of any staff decision to remove a board from the recognized list.

cc: Chairman Meserve
Commissioner Dicus
Commissioner 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: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend 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 authorized users, authorized medical physicists, authorized nuclear pharmacists or radiation safety officers. The proposed rule would also revise the 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.

DATES: The comment period expires **[insert date — 75 days from date of publication]**. Comments received after this date will be considered if it is practical to do so, but the NRC can only assure consideration for comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please refer to RIN 3150-AH19 in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available to the public in their entirety on the NRC rulemaking web site. Personal information will not be removed from your comments.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: SECY@ nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments on this proposed rule, as well as the draft Regulatory Analysis, via the NRC's rulemaking web site at http://ruleforum.llnl.gov. Address questions about our rulemaking website to Carol Gallagher (301) 415-5905; e-mail cag@nrc.gov.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm on Federal workdays (telephone (301) 415-1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101.

Publicly available documents related to this rulemaking may be examined and copied for a fee at the NRC's Public Document Room (PDR), Public File Area O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments, can be viewed and downloaded electronically via the NRC rulemaking web site at http://ruleforum.llnl.gov.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/NRC/ADAMS/index.html. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are

problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Roger W. Broseus, Office of Nuclear Material Safety and Safeguards, Mail Stop T9-C24, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone (301) 415-7608, e-mail, rwb@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

During development of the Part 35 proposed and final rules (August 13, 1998 (63 FR 43516); and April 24, 2002 (67 FR 20249), respectively), there was a general belief that the boards recognized by 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 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 certification and work experience. The only board that currently meets the revised requirements is the Certification Board of Nuclear Cardiology because it developed its certification program based on the final rule. The NRC staff held several discussions with the boards to determine whether the boards would modify their certifying process to meet all the requirements specified in the rule.

The current regulations in 10 CFR Part 35 offer three pathways for individuals to satisfy training and experience 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 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 the sake of this discussion, pathway (1) will be referred to as the certification pathway, and pathway (2) as the alternate pathway. For example, in § 35.50, the proposed criteria for meeting training and experience requirements for the certification pathway (1) appear in §35.50(a); those for the alternate pathway (2) appear in §35.50(b); and those for pathway (3) appear in §35.50(c).

On February 19, 2002, in a briefing of the Commission, the Advisory Committee on Medical Uses of Isotopes (ACMUI) expressed concern that if the draft final rule became effective as drafted, there could be potential shortage of individuals qualified to serve as RSOs, AMPs, ANPs and AUs. The ACMUI indicated that, without changes in the draft final rule, 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 on candidates using the certification pathway for approval. The extra requirements of concern to ACMUI include a specification for length-of-training as well as obtaining a written certification signed by a preceptor. Taken together with

other requirements of boards, such as requiring candidates for certification to take written and/or oral examination, the concern was that candidates seeking approval might bypass the board certification pathway and select the alternate pathway.

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) 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 ends 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 is to have this new rule in place before the end of the 2-year transition period.

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 10 CFR 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590, and 35.690.

The ACMUI formed a subcommittee to develop recommendations on the training and experience issue. A public subcommittee meeting was held on June 21, 2002, at NRC headquarters in Rockville, MD. Representatives from 13 boards, associations, and societies participated in the meeting. In addition, 8 boards and societies provided written comments to the ACMUI subcommittee on its recommendations. After considering the comments from the meeting and letters, the subcommittee developed final recommendations and submitted them to

the ACMUI for consideration.

The ACMUI full committee discussed the subcommittee's recommendations in a public tele-conference meeting on July 8, 2002. Members of the public and representatives from the Society of Nuclear Medicine participated in the tele-conference. The ACMUI approved the recommendations of the subcommittee and submitted them in a report to the NRC on August 1, 2002. The report provided a rationale for the recommendations accompanied by suggested rule language. 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 at Attachment 2. The three options were: Option (1) retain the existing requirements in the current regulations; Option (2) prepare a proposed rule to modify training and experience requirements based on the recommendations submitted by the ACMUI; and, Option (3) the same as Option 2 with a minor modification (i.e., listing all specialty boards recognized by NRC on the NRC's web site rather than, as recommended by ACMUI, listing some boards in the regulation and others on the web site).

In an SRM 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 boards be posted on the NRC's web site, 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. This form of attestation should be preserved both for the certification pathway and the alternate pathway.

The ACMUI briefed the Commission on May 28, 2003, and conveyed their views

regarding the Commission's direction to NRC staff, relating to preceptor statements, in SRM-02-0194 (February 12, 2003). The Commission subsequently issued an SRM on June 20, 2003 (M030528B). This SRM directed that the staff continue its development of a proposed rule to modify the training and experience requirements in 10 CFR 35, with appropriate interactions with the ACMUI, so that the revised rule can be in place as promptly as possible. The NRC staff met with the ACMUI via tele-conference on July 17, 2003, to further discuss the ACMUI's comments on the proposed rule.

Discussion

The principal changes proposed to 10 CFR Part 35 involve revising the criteria for recognizing the certifications of specialty boards. These changes relate to the requirements that boards would place on candidates seeking board certification in the area of training and experience. The changes would result in requirements that are less prescriptive while maintaining public health and safety. These changes would ensure that a clear regulatory determination can be made that all specialty boards, both new and existing, meet the relevant criteria for recognition by the NRC or an Agreement State. Minor changes would also be made to the training and experience requirements in the alternate pathway.

Certification Pathway.

For the certification pathway, the current regulations incorporated the more prescriptive requirements for the alternate pathway. The proposed rule would establish separate criteria that a board must meet to be recognized by the NRC or an Agreement State. For the RSO, AMP, and ANP, the proposed criteria include a degree from an accredited college or university,

professional experience, passing an examination administered by the board, obtaining a written preceptor statement, 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 requirements for a degree (baccalaureate, masters, or doctorate) and the amount of professional experience vary depending on what type of approval is sought (for RSO, AMP, or an ANP). The certification pathway also includes a specification for number of hours of training and experience for ANPs and AUs for uses of certain byproduct material under §§ 35.100, 35.200, 35.300 (in 35.390, 35.392, 35.394 for uses under 35.300), and 35.500.

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 Part 35, as previously discussed.

The proposed rule would provide the boards more latitude in making the determination that an individual is fully trained and capable of performing his or her duties in radiation safety. These proposed changes to the certification pathway would continue to ensure the safe use of byproduct material by medical licensees by establishing criteria for specialty boards to use in granting certifications. The prescriptive requirements for recognition of specialty board certifications would be removed.

Alternate Pathway.

The proposed rule also contains revised requirements for some of the alternate pathways. Most of these changes are minor and would clarify the requirements for training and experience.

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 above under the heading, "Certification Pathway."

Training Specific to Type of Use.

The ACMUI recommended that, in addition to meeting minimum training and experience requirements, authorized individuals should have training or experience in the use of byproduct material or specific modalities (type of use), as appropriate, for which a licensee is authorized. The requirement would also 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 would ensure that licensee's staff have adequate knowledge and experience to fulfill the duties for which they are responsible. The proposed rule includes new paragraphs that add this requirement in § 35.50(d) 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) provide for training specific to type of use which applies to both the board certification and alternate pathways.

Other Changes.

In the current rule, § 35.390(b)(1) specifies that work experience for uses of byproduct

material in unsealed form for which a written directive 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. Section 35.390(b)(1)(ii)(G)(3) and (4) refer to parenteral administration of certain radionuclides. The proposed rule would clarify that this training must be with quantities of radionuclides for which a written directive is required. The NRC supports these changes 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 written directive is required.

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. The proposed rule would effect 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). The NRC agrees with this recommendation because ensuring proper function of these instruments involves more than periodic calibration (e.g., checks of functionality, constancy); further, calibration is part of quality control procedures.

Training requirements for authorizations as a medical physicist would be changed in § 35.51(b)(1) to remove credit 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 would be changed to a more general requirement for 1 year of full-time training in medical physics. Similarly, the requirement for training in a clinical radiation oncology facility would be changed to a requirement for training in “clinical radiation facilities.” Pluralizing “facility” makes it

possible for candidates to receive training in more than one institution. In § 35.690.(b)(2), the requirement for candidates to be approved as AUs would be changed to broaden the requirement requiring 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 and allowing for T&E to be obtained in more than one facility.

Current regulations provide, in § 35.50(c), 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 radiation safety officer responsibilities. 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 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. A change to the regulations in § 35.50(c) is proposed that would allow medical physicists, who are certified by a specialty board recognized by the NRC or an Agreement State, to serve as RSOs, while retaining the requirement that individuals have experience specific to the types of use for which they would be responsible. This change would remove an impediment for individuals who have adequate T&E to becoming approved as RSOs. It would also avoid 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 in order to approve a licensee's request to have a medical physicist, certified by a recognized specialty board, serve

as an RSO.

The term “high energy” is used in the proposed rule text in § 35.51(a)(2)(ii) to specify the type of training to be included in T&E for AMPs. The NRC has not defined the term “high energy” because, to do so, would be overly prescriptive and such definition might be misinterpreted as establishing a threshold for the minimum photon energy for which experience with external beam therapy is appropriate to qualify as an AMP.

Preceptor Certification.

Part 35 currently requires a written certification that the individual has satisfactorily completed the required training and has achieved a level of knowledge or competency sufficient to function independently and that the written certification must be signed by a preceptor who is an authorized user, authorized medical physicist, authorized nuclear pharmacist, or radiation safety officer. 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 certification.

The Commission considered the ACMUI recommendations and determined that the preceptor statement should remain as written in the current rule (published on April 24, 2002). However, the Commission has 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.

Listing of Recognized Boards.

The NRC would list on its web site, instead of in its regulations, the names of boards whose certification process meets the NRC's criteria. 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.

Boards that are currently listed in Subpart J of Part 35 and other boards would be required to apply for recognition under this rule. NRC staff will review a board's submittal with the ACMUI before a decision on recognition of a board is made. The NRC plans to place the procedures for listing and de-listing of specialty boards on its web site before the effective date of the final rule, if adopted.

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 meeting was conducted as a facilitated, roundtable discussion with representatives of specialty boards; members of the public also had the opportunity to present their views. NRC staff also made a presentation to the ACMUI on May 20, 2003, regarding the staff's approach to the proposed rule; subsequent to this, further input was obtained from the Chair of the ACMUI and the Chair of the ACMUI subcommittee, feedback was received via e-mail from a participant in the meeting with the boards.

A draft of this Federal Register Notice was sent to the Agreement States and the ACMUI for 30-day review and comment. A tele-conference between NRC staff and ACMUI was held on July 17, 2003; approximately 12 Agreement State representatives participated in this conference, notice of which appeared in the Federal Register on July 14, 2003 (68 FR 41665). Comments of

the ACMUI, Agreement States, board members, and members of the public provided useful information to the NRC in preparing the proposed rule. A person from the State of Alabama represented the Organization of Agreement States and participated as a member of the working group with the NRC staff in the development of this proposed rule.

Recommendations of the ACMUI.

At the teleconference held on July 17, 2003, the full ACMUI discussed the draft proposed rule. During the teleconference, the ACMUI approved 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 paragraph § 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 § 35.390(a)(1) for uses under § 35.600. Secondly, the ACMUI recommended that the experiential requirements, 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 adopted because the NRC staff believes 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 written directive is required. Furthermore, if the requirement were removed from the certification pathway, individuals and applicants for licenses, or amendments, would be required to provide documentation of completion of requirements for experience required under § 35.390(b)(1)(ii)(G), in addition to evidence of board certification, to gain approval as AUs.

Therefore, this requirement was retained in the proposed rule. Thirdly, the ACMUI recommended that the requirement for a preceptor statement be separated from the board certification pathway and the alternate pathway, and specified separately as a new paragraph in each training section. Lastly, the ACMUI recommended that the word "attest" should be used in place of certify (certification) in preceptor statements. ACMUI explained that the reason for this recommendation was to reflect the current practice that preceptors do not "certify" individuals, but "attest." The NRC is inviting comment on the issue of whether the word "attestation" should be used in place of the word "certification" in preceptor statements.

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 Part 35 published on April 24, 2002. For Agreement States to adopt the proposed training and experience requirements contained in this proposed rule and have them in place by October 24, 2005, the Agreement States would have a shortened time frame for developing compatible requirements. Agreement States have voiced concern regarding this shortened time frame. Therefore, the NRC is inviting comment on the issue of whether Agreement States should establish the requirements to conform with this proposed rule by October 24, 2005, or whether they should follow the normal process and be given a full 3 years to develop a compatible rule.

Section by Section Analysis

Section 35.50 - Training for Radiation Safety Officer.

This section would be amended to modify the requirements that must be met as part of a

specialty board certification process for the specialty board 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) would be amended to provide separate requirements for a specialty board's certification process. This process would include a requirement to pass an examination, administered by diplomates of the specialty board, which would evaluate knowledge and competency areas that are important to functioning as a radiation safety officer. Paragraph (c) would be modified to allow medical physicists to serve as RSOs if they are certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. A new paragraph (d) would be added to require training in radiation safety, regulatory issues, and emergency procedures for the types of use for which an applicant seeks authorization. Paragraph (d) would apply to all pathways.

Section 35.51 - Training for an authorized medical physicist.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board 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) would be amended to provide separate requirements for a specialty board's certification process. This process would include a requirement to pass an examination, administered by diplomates of the specialty board, which would evaluate knowledge and competency areas that are important to functioning as a medical physicist. A new paragraph (c) would be 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) would apply to all pathways. In addition, for the alternate pathway (paragraph (b)(1)), the acceptable areas of

concentration for degrees would be expanded, and a requirement that the degree be from an accredited college or university would be added. Paragraph (b)(1) would also be amended to list the specific areas for which the individual needs to have training and work experience, instead of referring to other sections of Part 35. Requirements that training be received in an oncology facility would be generalized by removing the word oncology and "facility" would be pluralized to allow for training to be gained in more than one facility.

Section 35.55 - Training for an authorized nuclear pharmacist.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board 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) would be amended to provide separate requirements for a specialty board's certification process. This certification process would include a requirement to pass an examination, administered by diplomates of the specialty board, which would evaluate knowledge and competency areas that are important to functioning as a nuclear pharmacist.

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

Paragraph (a) would be amended to change "October 24, 2002," to the effective date of the final rule, if adopted.

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

Paragraph (a) would be amended to modify the requirements that must be met as part of

a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under § 35.100. A requirement would be added that candidates must pass an examination administered by diplomates of the specialty board. Additionally, paragraph (c)(1)(ii)(B) would be 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.

Section 35.290 - Training for imaging and localization studies.

Paragraph (a) would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under § 35.200. A requirement would be added that candidates must pass an examination, administered by diplomates of the specialty board. Additionally, paragraph (c)(1)(ii)(B) would be 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.

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

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under § 35.900. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would be amended to provide separate requirements for a specialty board's certification process. Paragraph (b)(1)(ii)(B) would be 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. In addition, paragraphs (b)(1)(ii)(G)(3) and (4) would be amended to revise the work experience requirement for individuals requesting AU status involving parenteral administration of dosages to limit it to those cases for which written directives are required.

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) would be amended to include a statement that the recognized boards would be posted on the NRC's web page. Paragraph (c)(2)(ii) would be amended to modify the requirement that 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.

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) would be amended to include a statement that the recognized boards will be posted on the NRC's web page. Paragraph (c)(2)(ii) would be amended to modify the requirement that 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.

Section 35.490 - Training for use in manual brachytherapy sources.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board 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) would provide separate requirements for a specialty board's certification process. Additionally, paragraph (b)(2) would be 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 35.590 - Training for use of sealed sources for diagnosis.

Paragraph (a) would be amended to include a statement that recognized boards would be posted on the NRC's web page. Paragraph (b)(5) would be redesignated as paragraph (c) and would apply to both the certification and the alternate pathways. This revision would separate 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 would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board 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) would be amended to provide separate requirements for a specialty board's certification process. Additionally, for the alternate pathway, paragraph (b)(2) would be 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) would be modified to allow for experience in "radiation therapy." A new paragraph (c) would be added to require training in device operation, safety procedures, and clinical use for the type(s) of use for which approval as an authorized user is sought. Paragraph (c) would apply to all pathways.

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 proposed rule would be a matter of compatibility between NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. The Compatibility Categories for the sections amended in this proposed rule would be the same as the sections in the current regulations. The revisions to §§35.50, 35.51, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.491, 35.590, and 35.690 are classified as Category B. 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.

Plain Language

The Presidential Memorandum dated June 1, 1998, entitled, "Plain Language in Government Writing" directed that the Government's writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31883). The NRC requests comments

on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the heading “ADDRESSES” above.

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 proposed rule, the NRC would modify the training and experience requirements for authorized users, authorized medical physicists, authorized nuclear pharmacists, and radiation safety officers. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

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, if adopted, would not be 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 Nuclear Regulatory Commission (NRC) is proposing to amend 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 authorized users, authorized medical physicists, authorized nuclear pharmacists or radiation safety officers. The proposed rule would also revise the 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 Proposed Action.

The proposed action under consideration is an amendment to the Commission's regulations governing the medical use of byproduct materials (Part 35). The proposed action would change 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 authorized users, authorized medical physicists, authorized nuclear pharmacists or radiation safety officers. The proposed action would also amend certain requirements for the training and experience of individuals who do not choose the board certification pathway.

During its revision of Part 35, the Commission became aware that, as a result of the changes to its training and experience requirements, specialty boards 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 into the final rule which was published in the Federal Register on April 24, 2002 (67 FR 20249). Subpart J is effective for a two-year transition period

which will expire on October 24, 2004. The proposed action would address this issue relating to recognition of board certifications after expiration of the two-year transition period.

Need for the Proposed 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 expires on October 24, 2004, and without this rulemaking, there could be a potential shortage of authorized individuals for medical procedures involving the use of byproduct material.

Alternatives to the Proposed Action.

An alternative to the proposed action would be to take no action. Subpart J will 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 Proposed 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 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 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 proposed revisions to the training and experience requirements in Part 35. The revisions currently under consideration also focus on the knowledge and experience that is integral to radiation safety. The proposed amendments to 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 Part 35 rulemaking, published in the Federal Register (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. NRC staff have determined that the proposed 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. §§ 1531 et seq). Likewise, the NRC staff have determined that the proposed 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. §§ 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. However, the general public should note that the NRC seeks public participation. Comments on any aspect of the Environmental Assessment may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of this proposed rule to every State Liaison Officer and requested their comments on the environmental assessment.

Paperwork Reduction Act Statement

This proposed rule would amend information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The burden includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The proposed rule would revise the criteria for recognition of specialty board whose certification may be used to demonstrate the adequacy of training and experience of individuals to serve as authorized users, authorized medical physicists, authorized nuclear pharmacists or radiation safety officers. The proposed rule would also revise the requirements for demonstrating the adequacy of training and experience for the alternate pathway. The change in burden for information collection relates to submission and review of applications of specialty boards for recognition and is estimated to be insignificant. Because the burden for this information collection is insignificant, Office of Management and Budget (OMB) clearance is not required. Existing requirements were approved by the Office of Management and Budget, approval number 3150-

0010.

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.

Regulatory Analysis

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

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading. The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Public File Area O1F21, 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, e-mail, rwb@nrc.gov.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission -

certifies that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. The Nuclear Regulatory Commission (NRC) is proposing to amend 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 authorized users, authorized medical physicists, authorized nuclear pharmacists or radiation safety officers. The proposed rule would also revise the requirements for demonstrating the adequacy of training and experience of individuals who do not choose pathways other than the board certification pathway. The regulatory flexibility analysis prepared for the final rule on Part 35 (67 FR 20249; April 24, 2002) indicated that about 740 out of 1688 licensees could be considered small entities. The proposed rule should have no burden or economic impact on licensees because it does not add new requirements; it would provide a revision to an existing option.

Any small entity subject to this regulation that determines, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this opinion in a comment that indicates --

(a) The licensee's size and how the proposed regulation would result in a significant economic burden upon the licensee as compared to the economic burden on a larger licensee;

(b) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities;

(c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulations were modified as suggested by the licensee;

(d) How the proposed regulation, as modified, would more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individual or group; and

(e) How the proposed regulation, as modified, would still adequately protect public health and safety.

Backfit Analysis

The Commission has determined that the backfit rule does not apply to this proposed rule because these amendments would not involve any provision that would impose backfits as defined in 10 CFR Chapter 1. Therefore, a backfit analysis is not required for this proposed rule.

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. 553; the NRC is proposing to adopt 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).

2. In §35.50, paragraphs (a) and (c) are revised, and paragraph (d) is 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. (Specialty Boards whose certification process has 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) 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;

(2) 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 three years in applied health physics;

(3) 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; and

(4) Obtain written certification signed by a preceptor radiation safety officer that the individual has achieved a level of radiation safety knowledge sufficient to function independently

as a radiation safety officer for a medical use licensee; or

* * * * *

(c) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license, or 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 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 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 an authorized medical physicist, authorized user, authorized nuclear pharmacist, or radiation safety officer, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

3. 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. (Specialty Boards whose certification process has 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) 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 and brachytherapy services under the direction of physicians who meet the requirements for authorized users in §§ 35.490 or 35.690;

(3) Pass an examination, administered by diplomates of the specialty board, 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; and

(4) Obtain written certification that the individual has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic use for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51 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; 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 modalities 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 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 certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) 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 certification must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51 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 in the modalities 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.

4. In § 35.55, paragraph (a) is 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. (Specialty Boards whose certification process has 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) Have graduated from a pharmacy program accredited by the American Council On Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

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

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

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, which 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; and

(5) Obtain written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist; or

* * * * *

§ 35.57 [Amended]

5. In § 35.57, replace both references to “October 24, 2002" with “[insert effective date of final rule]”.

6. In § 35.190, paragraphs (a) and (c)(1)(ii)(B) 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. (Specialty Boards whose certification process has 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) Meet the requirements in paragraph (c)(1) 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; and

(3) Obtain written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, that the individual has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100; or

* * * * *

(c) * * *

(1) * * *

(ii) * * *

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

* * * * *

7. In § 35.290, paragraphs (a) and (c)(1)(ii)(B) 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. (Specialty Boards whose certification process has 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) Satisfy the requirements in paragraph (c)(1) 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; and

(3) Obtain written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, that the individual 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; or

* * * * *

(c) * * *

(1) * * *

(ii) * * *

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

* * * * *

8. In § 35.390 paragraph (a), paragraphs (b)(1)(ii)(B), and (b)(1)(ii)(G)(3) and (4) are revised to read as follows:

§ 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. (Specialty Boards whose certification process has 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 a minimum of three years of residency training in a radiation oncology or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in paragraph (b)(1) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;

(2) 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; and

(3) Obtain written certification that the individual has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in §§ 35.390(a), 35.390(b)(1), or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b)(1), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status; or

(b) * * *

(1) * * *

(ii) * * *

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

* * * * *

(G) * * *

(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.

* * * * *

9. In § 35.392, paragraphs (a) and (c)(2)(ii) 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 paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification process has 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;

* * * * *

10. In § 35.394, paragraphs (a) and (c)(2)(ii) 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 paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification process has 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;

* * * * *

11. In § 35.490, paragraphs (a) and (b)(2) 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. (Specialty Boards whose certification process has 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 a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;

(2) 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 high and low dose-rate brachytherapy; and

(3) Obtain written certification, signed by a preceptor authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, that the individual 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; 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 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

* * * * *

12. 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. (Specialty Boards whose certification process has 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;

(4) Radiation biology; and

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

13. 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. (Specialty Boards whose certification process has 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 a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;

(2) 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, high and low dose-rate brachytherapy, and external beam therapy; and

(3) Obtain written certification that the individual 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 certification must be signed by a preceptor authorized user who meets the requirements in § 35.690 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;

(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 equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) 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 certification must be signed by a preceptor authorized user who meets the requirements

in § 35.690 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.

Dated at Rockville, Maryland, this_____ day of_____, 2003.

For the Nuclear Regulatory Commission.

_____
Annette Vietti-Cook,
Secretary of the Commission.

Georgetown University Hospital

Manuel D. Cerqueira, M.D.
Associate Chief of Cardiology
Professor of Medicine & Radiology
Director of Nuclear Cardiology & Exercise Stress Testing Laboratories

Department of Medicine
Division of Cardiology

7/23/03

Thomas H. Essig
Designated Federal Official
ACMUI
U.S. Nuclear Regulatory Commission

RE: Preceptor attestation in sections 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490

Dear Mr. Essig:

The purpose for this memo is to restate the consensus position of ACMUI that a preceptor attestation should not be a requirement for specialty boards to qualify under 10 CFR 35 sections that specify training requirements for radiation safety officers, authorized medical physicists, authorized nuclear pharmacists, or authorized users.

The criteria for recognition of specialty boards should not include the requirement that candidates for certification obtain written attestation of competency signed by a preceptor. Specialty boards assess mastery of a body of knowledge and adequacy of judgment to independently practice health physics, medical physics, nuclear pharmacy, or a medical radiation specialty. Each board has a process to assure that candidates are knowledgeable before they take the board exams. This process includes a requirement that the candidate's supervisor and other professionals provide letters of recommendation attesting to the knowledge of the candidate. In many cases the supervisor is a preceptor as defined in Part 35. The letters do not attest to an individual's ability to function independently in a specific position, because the individual may not be applying for that specific position, e.g. medical radiation safety officer. For example, candidates for the American Board of Health Physics do not all become medical radiation safety officers; many become regulators, nuclear power health physicists, or health physicists in academia or industry. Therefore, the letters attest to the candidate's knowledge in health physics. Attestation by a preceptor as defined in Part 35 training and education sections is neither needed nor desired in the board certification pathway. Thus, the ACMUI restates its recommendation that the requirements for a preceptor statement be removed from the certification pathway.

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If the Commission still feels it is necessary to include a preceptor statement for all authorized positions named in Part 35, the ACMUI recommends that this requirement be separated from the board certification pathway and the alternate pathway and specified separately as a new paragraph in each training section. For example, in section 35.50, remove the requirement for a preceptor attestation from both the board pathway and alternate pathway and add a new paragraph that would require the licensee to obtain an attestation, signed by a preceptor Radiation Safety Officer, that the individual has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

Thank you for your attention to this matter.

Sincerely,

Manuel D. Cerqueira, M.D.
Chair
ACMUI

Ccc: Charles Miller
Patricia Holahan

Alternate Language for FRN

Alternate text for FRN to implement the ACMUI's recommendation to remove the requirement for a preceptor statement from criteria for NRC or Agreement State recognition of specialty board certifications.

Changes to Discussion: Under the heading Certification Pathway, remove the phrase "obtaining a written preceptor statement" from the third sentence.

Addition to Discussion: Insert the following between paragraphs 3 & 4 under the heading Certification Pathway.

During the tele-conference with ACMUI, conducted on July 17, 2003, ACMUI members continued to voice concern about having recognition of boards 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 Part 35, this requirement be separated from the criteria for recognition of board certifications, as well as the alternative pathway. Agreement State representatives participating in the tele-conference agreed with this recommendation. In a letter, dated July 23, 2003, Dr. Manuel Cerqueira, Chair of the ACMUI, restated the ACMUI's recommendation that the requirements for a preceptor statement be removed from the certification pathway; however, if the Commission still felt it necessary to include a preceptor statement for all authorized positions named in Part 35, the ACMUI recommended that this requirement be separated from the board certification pathway and the alternate pathway and specified separately as a new paragraph in each training section. The NRC has adopted ACMUI' s recommendation because it retains the requirement of obtaining preceptor statements in order to satisfy the training required by both the board certification and alternate pathways, while placing the responsibility upon the individual seeking authorized status to obtain the preceptor statement.

Changes to Section by Section: Substitute the following at appropriate points in the "Section by Section Analysis."

Section 35.50 - Training for Radiation Safety Officer.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board 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) would be amended to provide separate requirements for a specialty board's certification process. This process would include a requirement to pass an examination, administered by diplomates of the specialty board, which would evaluate knowledge and competency areas that are important to functioning as a radiation safety officer. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as a radiation safety officer. Paragraph (c) would be modified to allow medical physicists to serve as RSOs if they are certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. A new paragraph (d) would be added to require training in radiation safety, regulatory issues, and emergency procedures for the types of use for which an applicant seeks authorization. Paragraph (d) would apply to all pathways.

Section 35.51 - Training for an authorized medical physicist.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board 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) would be amended to provide separate

requirements for a specialty board's certification process. This process would include a requirement to pass an examination, administered by diplomates of the specialty board, which would evaluate knowledge and competency areas that are important to functioning as a medical physicist. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an authorized medical physicist. A new paragraph (c) would be 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) would apply to all pathways. In addition, for the alternate pathway (paragraph (b)(1)), the acceptable areas of concentration for degrees would be expanded, and a requirement that the degree be from an accredited college or university would be added. Paragraph (b)(1) would also be amended to list the specific areas for which the individual needs to have training and work experience, instead of referring to other sections of Part 35. Requirements that training be received in an oncology facility would be generalized by removing the word oncology and "facility" would be pluralized to allow for training to be gained in more than one facility.

Section 35.55 - Training for an authorized nuclear pharmacist.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board 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) would be amended to provide separate requirements for a specialty board's certification process. This certification process would include a requirement to pass an examination, administered by diplomates of the specialty

board, which would evaluate knowledge and competency areas that are important to functioning as a nuclear pharmacist. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an authorized nuclear pharmacist.

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

Paragraph (a) would be amended to change “October 24, 2002," to the effective date of the final rule, if adopted.

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

Paragraph (a) would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under § 35.100. A requirement would be added that candidates must pass an examination administered by diplomates of the specialty board. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an authorized user under § 35.100. Additionally, paragraph (c)(1)(ii)(B) would be 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.

Section 35.290 - Training for imaging and localization studies.

Paragraph (a) would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under § 35.200. A requirement would be added that candidates must pass an examination, administered by diplomates of the specialty board. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an authorized user under § 35.200. Additionally, paragraph (c)(1)(ii)(B) would be 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.

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

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under § 35.900. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would be amended to provide separate requirements for a specialty board's certification process. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an authorized user under § 35.300. Paragraph (b)(1)(ii)(B) would be 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. In addition, paragraphs (b)(1)(ii)(G)(3) and (4) would be amended to revise the

work experience requirement for individuals requesting AU status involving parenteral administration of dosages to limit it to those cases for which written directives are required.

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) would be amended to include a statement that the recognized boards would be posted on the NRC's web page. Paragraph (c)(2)(ii) would be amended to modify the requirement that 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.

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) would be amended to include a statement that the recognized boards will be posted on the NRC's web page. Paragraph (c)(2)(ii) would be amended to modify the requirement that 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.

Section 35.490 - Training for use in manual brachytherapy sources.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board 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) would provide separate requirements for a

specialty board's certification process. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an authorized user under § 35.400. Additionally, paragraph (b)(2) would be 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 35.590 - Training for use of sealed sources for diagnosis.

Paragraph (a) would be amended to include a statement that recognized boards would be posted on the NRC's web page. Paragraph (b)(5) would be redesignated as paragraph (c) and would apply to both the certification and the alternate pathways. This revision would separate 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 would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board 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) would be amended to provide separate requirements for a specialty board's certification process. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as

an authorized user under § 35.600. Additionally, for the alternate pathway, paragraph (b)(2) would be 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) would be modified to allow for experience in "radiation therapy." A new paragraph (c) would be added to require training in device operation, safety procedures, and clinical use for the type(s) of use for which approval as an authorized user is sought. Paragraph (c) would apply to all pathways.

Changes to rule text: Substitute the following at appropriate points in the Rule Text.

(The NRC staff notes that conforming changes to §§ 35.13 and 35.14 would be required should the following changes to the proposed rule text be approved by the Commission.)

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. 553; the NRC is proposing to adopt 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:

PART 35 - MEDICAL USE OF BYPRODUCT MATERIAL

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).

2. In §35.50, paragraphs (a) and (c) are revised, and paragraph (d) is 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. (Specialty Boards whose certification process has 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) 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;

(2) 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 three years in applied health physics; and

(3) 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

(b) * * *

(c) Has obtained written certification, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (a) or (b) 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; or

(d) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license, or 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 with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; 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 an authorized medical physicist, authorized user, authorized nuclear pharmacist, or radiation safety officer, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

3. 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. (Specialty Boards whose certification process has 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) 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 and brachytherapy services under the direction of physicians who meet the requirements for authorized users in §§ 35.490 or 35.690;

(3) Pass an examination, administered by diplomates of the specialty board, 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; 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 modalities 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 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

(c) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (a) or (b)(1) 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 certification must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51 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

(d) Has training for the type(s) of use in the modalities 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.

4. In § 35.55, paragraph (a) is revised and paragraph (c) is added 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. (Specialty Boards whose certification process has 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) Have graduated from a pharmacy program accredited by the American Council On Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

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

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

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, which 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) * * *

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

§ 35.57 [Amended]

5. In § 35.57, replace both references to “October 24, 2002" with “[insert effective date of final rule]”.

6. In § 35.190, paragraphs (a) and (c)(1)(ii)(B) are revised and paragraph (d) is added 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. (Specialty Boards whose certification process has 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) Meet the requirements in paragraph (c)(1) 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

* * * * *

(c) * * *

(1) * * *

(ii) * * *

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

* * * * *

(d) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a) 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.

* * * * *

7. In § 35.290, paragraphs (a) and (c)(1)(ii)(B) are revised and paragraph (d) is added 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. (Specialty Boards whose certification process has 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) Satisfy the requirements in paragraph (c)(1) 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

* * * * *

(c) * * *

(1) * * *

(ii) * * *

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

* * * * *

(d) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a) 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.

* * * * *

8. In § 35.390 paragraph (a), paragraphs (b)(1)(ii)(B), and (b)(1)(ii)(G)(3) and (4) are revised and paragraph (c) is added to read as follows:

§ 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. (Specialty Boards whose certification process has 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 a minimum of three years of residency training in a radiation oncology or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in paragraph (b)(1) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;

(2) 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; or

(b) * * *

(1) * * *

(ii) * * *

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

* * * * *

(G) * * *

(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

(c) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (a) 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 certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status.

* * * * *

9. In § 35.392, paragraphs (a) and (c)(2)(ii) are revised and paragraph (d) is added 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 paragraph (c)(1) and (2) of this section and whose certification has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification process has 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;

* * * * *

(d) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (a) or (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 certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.392, § 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2).

10. In § 35.394, paragraphs (a) and (c)(2)(ii) are revised and paragraph (d) is added 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 paragraph (c)(1) and (2) of this section and whose certification has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification process has 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;

* * * * *

(d) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (a) or (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 certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2).

11. In § 35.490, paragraphs (a) and (b)(2) are revised and paragraph (c) is added 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. (Specialty Boards whose certification process has 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 a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;

(2) 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 high and low dose-rate 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 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

(c) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) 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.

* * * * *

12. 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. (Specialty Boards whose certification process has 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;

(4) Radiation biology; and

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

13. 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. (Specialty Boards whose certification process has 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 a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;

(2) 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, high and low dose-rate brachytherapy, 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 equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review

Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(c) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (a) 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 each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690 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

(d) 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.

REGULATORY ANALYSIS

PROPOSED RULE

10 CFR PART 35 – RECOGNITION OF SPECIALTY BOARDS

BACKGROUND:

The Nuclear Regulatory Commission (NRC) is proposing to amend 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 authorized users, authorized medical physicists, authorized nuclear pharmacists or radiation safety officers. The proposed rule would also revise the 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.

During development of proposed and final rules for Part 35 (August 13, 1998 (63 FR 43516) and April 24, 2002 (67 FR 20249), respectively), there was a general belief that the boards recognized by the NRC at that time 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 they 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, the Advisory Committee on Medical Uses of Isotopes (ACMUI) briefed the Commission and expressed a concern that if the final rule, as drafted, became effective, there could be shortage of individuals qualified to serve as a radiation safety officer (RSO), authorized medical physicist (AMP), authorized nuclear pharmacist (ANP) and authorized user (AU). 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 training and experience (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 tele-conference meeting on July 8, 2002. The ACMUI submitted recommendations in a report, including suggested rule language, to the NRC on August 1, 2002. The staff provided options for addressing the T&E requirements in SECY-02-0194 dated October 30, 2002. On February 12, 2003, the Commission issued an SRM-02-0194 (Attachment 1), responding to SECY-02-0194, that approved preparing a proposed rule to modify the T&E requirements, based on the ACMUI's recommendations.

Changes proposed to T&E requirements relate to two pathways to 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 satisfy NRC requirements for T&E, termed herein the "certification pathway." A second pathway, termed herein 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 would involve revising the criteria for the certification pathway so that the requirements are less prescriptive than those in the current rule. The proposed rule would revise the criteria that a board must meet to be recognized by the NRC or an Agreement State. The proposed 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, obtaining a written preceptor statement, as well as clarifying that individuals are to have T&E related to the type of use (termed "modality" by the ACMUI) for which they would be responsible. The required degree (baccalaureate, masters, or doctorate) and the amount of professional experience varies depending on what type of approval is sought (for RSO, AMP, or an ANP). The certification pathway also includes a specification for number of hours of T&E for ANPs and authorized users (AUs) for uses of

certain byproduct material under §§ 35.100, 35.200, 35.300 (in 35.390, 35.392, 35.394 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 Part 35.

1. T&E Requirements

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

2. Preceptor Certification

Under the regulations in the former Part 35, preceptor certification was not required for board certification. The current regulations require preceptor certification including a signature by an authorized individual. This requirement applies to both certification and the alternate pathway. Some boards require certification by a qualified individual, such as the program director. However, this qualified individual need not necessarily be an authorized individual, as required of a preceptor by the final rule.

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

certification; and (2) in the case of the board certification process, whether the members of the board could collectively act as a "preceptor."

3. New Types of Use

The T&E requirements in the current Part 35 were expanded to address two new types of use that were not considered in the former rule (i.e., remote after loader units and gamma stereotactic radiosurgery units, as described in 10 CFR 35.690). These requirements were geared to address unique health and safety issues 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 Part 35; and (2) carrying out a rulemaking to modify T&E requirements to address the concerns noted above.

Option 1 (No Action) would leave unchanged the requirements of the T&E sections of 10 CFR Part 35, and would require the boards to modify their certification programs as necessary to comply with the specified requirements. If the boards chose not to change, their certification process would not be recognized by the NRC after the expiration of Subpart J on October 24, 2004. Candidates who desired to become approved as an RSO, AMP, ANP or AU would have to meet requirements for T&E in the alternate pathway. The burden associated with seeking approval via the alternate pathway would be increased because licensees would have to submit applications for amendments and receive NRC approval before individuals could serve in the capacity for which approval would be sought. If boards chose not to modify their programs, the issue of a potential shortage of authorized individuals would not be resolved.

Under Option 2 (Rulemaking), the NRC would implement a rulemaking to modify the regulations to specify new T&E criteria for recognition of board certification processes. The regulations

would continue to specify T&E requirements for individuals seeking approval as RSO, AMP, ANP or AU, specify separate T&E requirements for new types of use, and continue to require that boards include a requirement for certification to be signed by a preceptor approved by the NRC or an Agreement State for the type of approval sought. Under this option, the concerns regarding the radiation safety for new types of use the preceptor certification would be resolved. Option 2 is expected to increase stakeholder confidence because of the avoidance of concerns over potential disruption of medical services due to a shortage of individuals approved to serve as RSOs, AMPs, ANP, and AUs.

The NRC would list on its web site, rather than in its regulations, those boards recognized by the NRC or an Agreement State. This approach would have the advantage of avoiding the need to go through a rulemaking to list 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 existing regulations, proposed changes, and the estimated values and impacts of the rulemaking.

Training for Radiation Safety Officer (§ 35.50).

Existing Regulations

Section 35.50 specifies the training 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 speciality 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. The individual must also obtain written certification, signed by a preceptor RSO, that the individual has completed the required training and the individual has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee.

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 types of use(s) of byproduct material involving specified experience. The individual must also obtain written certification, signed by a preceptor RSO, that the individual has completed the required training and the individual has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee.

Alternatively, under § 35.50(c), the individual is required to be an authorized user, an authorized medical physicist, or authorized nuclear pharmacist 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.

Proposed Rule Changes

The proposed rule removes the requirement that the board certification process includes all of the training and experience requirements in § 35.50(b). The proposed rule establishes a number of less prescriptive training and experience requirements for the certification pathway. A proposed change to § 35.50(c) allows 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 proposed rule also adds an additional requirement to the T&E requirements in paragraph (b) that requires training in radiation safety, regulatory issues, and emergency procedures for the types of uses for which an applicant seeks authorization.

Cost Impacts:

NRC estimates that approximately 190 individuals will seek to become radiation safety officers under § 35.50 annually. Of these, 90 percent, or 171, will seek certification by a certifying board

under § 35.50(a). The NRC estimates that the remainder, or approximately 19 individuals, will seek to become radiation safety officers under § 35.50(b).[1]

The proposed new requirements for the certification pathway provide more flexibility than the current requirements. The proposed 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 proposed experience requirement, 5 or more years of appropriate professional experience including 3 in applied health physics (graduate training may be substituted for some of this) is also more flexible than current experience requirements.

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 Boards by the NRC and the Agreement States more efficient. No quantitative estimates of cost savings can be made.

Health and Safety Impacts:

None anticipated.

Benefits:

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

Training for authorized medical physicist (§ 35.51).

Existing Regulations

[1] These estimates, and similar estimates for other sections of 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.

Section 35.51 specifies the training requirements for an authorized medical physicist.

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

Alternatively, § 35.51(b) specifies training and experience requirements that may be met in lieu of certification by one of the listed speciality boards. It currently requires holding a master's or doctor's degree in one of four areas. In addition, one year of full time training in therapeutic radiological physics followed by one year of full time work experience under appropriate supervision at a medical institution that includes performing specified tasks is required.

Section 35.51(b)(2) contains a requirement that the candidate medical physicist must obtain written certification, signed by a preceptor authorized medical physicist, that the training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized medical physicist; this applies to the board certification pathway as well.

Proposed Rule Changes

The proposed rule removes the requirement that the certification pathway includes all of the training and experience requirements in § 35.51(b). Instead, the proposed rule establishes a number of less prescriptive training and experience requirements for the certification pathway. The proposed rule also adds an additional requirement to the T&E requirements in paragraph (b) that requires training in the type of use for which an applicant seeks authorization.

Cost Impacts:

NRC estimates that approximately 100 medical physicists will seek to become authorized medical physicists under § 35.51 or equivalent Agreement State regulations annually. Of these, 90 percent, or 90, will seek certification by a certifying board under § 35.51(a). The NRC

estimates that the remainder, or approximately 10 physicists, will seek to become authorized medical physicists under § 35.51(b).

The proposed new requirements for the certification pathway provide more flexibility than the current requirements. The proposed 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 proposed 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.

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 Boards by the NRC and the Agreement States more efficient. No quantitative estimates of cost savings can be made.

Health and Safety Impacts:

None anticipated.

Benefits:

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

Training for an authorized nuclear pharmacist (§ 35.55).

Existing Regulations

Section 35.55 specifies the training requirements for an authorized nuclear pharmacist.

Section 35.55(a) provides that the licensee shall require an authorized nuclear pharmacist to be certified by a speciality 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: (1) the pharmacist to have completed 700 hours in a structured educational program consisting of both didactic training in specified subjects and supervised practical experience in a nuclear pharmacy performing specified tasks; and (2) to have obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the didactic training and supervised practical experience and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist; this requirement also applies to the board certification pathway.

Proposed Rule Changes.

The proposed rule would remove the requirement that the certification pathway includes all of the training and experience requirements in § 35.51(b). The proposed rule would also establish a number of less prescriptive training and experience requirements for the board certification process.

Cost Impacts:

NRC estimates that approximately 20 pharmacists will seek to become authorized nuclear pharmacists under § 35.55 or equivalent Agreement State regulations annually. Of these, 90 percent, or 19 pharmacists, will seek certification by a certifying board under § 35.55(a). The NRC estimates that the remainder, or approximately one pharmacist, will seek to become an authorized nuclear pharmacist under § 35.55(b).

The proposed new requirements for the certification pathway provide more flexibility than the current requirements. The proposed 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 proposed experience requirement, 4,000 hours (academic training may be substituted for some of this), is also more flexible than current experience requirements.

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 Boards by the NRC and the Agreement States more efficient. No quantitative estimates of cost savings can be made.

Health and Safety Impacts:

None anticipated.

Benefits:

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

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

Existing Regulations

Section 35.190 specifies the training requirements for an authorized user of a radiopharmaceutical for uptake, dilution, and excretion studies.

Section 35.190(a) provides that the licensee shall require the authorized user of unsealed byproduct material for uptake, dilution, and excretion studies to be a physician who is certified by a speciality board whose certification process includes all of the requirements in § 35.55(c) and whose certification has been recognized by the Commission or an Agreement State.

Section 35.190(b) permits individuals to serve 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 training and experience 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; must have work experience under the supervision of an authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements in specified areas; and must have obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the classroom and laboratory training and work experience requirements and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100. The requirement for a preceptor statement also applies to the board certification pathway.

Proposed Rule Changes

The proposed rule would modify the criteria for approval of board certifications and make minor changes to the alternate pathway.

Cost Impacts:

NRC estimates that approximately 110 physicians seek to become authorized users under § 35.190 or equivalent Agreement State regulations annually. Of these, 90 percent, or 99 physicians, seek certification by a certifying board under § 35.190(a). The NRC estimates that the remainder, or approximately 11 physicians, seek to become authorized users under § 35.190(c).

The addition of an additional user pathway will add flexibility to the process, and result in enhanced regulatory efficiency. No quantitative estimates of cost savings can be made.

Health and Safety Impacts:

None anticipated.

Benefits:

Authorized users would have training and experience commensurate with risk and focused on radiation safety.

Training for imaging and localization studies (§ 35.290).

Existing Regulations

§ 35.290 specifies the training requirements for an authorized user of radiopharmaceuticals and generators for imaging and localization studies.

§ 35.290 (a) provides that the licensee shall require the authorized user to be a physician who is certified by a speciality 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.

§ 35.290(b) acknowledges physicians who are authorized users 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 training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include classroom and laboratory training in specified areas and work experience, under the supervision of an authorized user who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, involving specified activities. The physician must have obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the classroom and laboratory training and work experience required under § 35.290(c) 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. Authorized users approved under the board certification pathway must also obtain a preceptor statement.

Proposed Rule Changes

The proposed rule would modify the criteria for approval of board certifications and make minor changes to wording of requirements for the alternate pathway.

Cost Impacts:

NRC estimates that approximately 110 physicians will seek to become authorized users under § 35.290 or equivalent Agreement State regulations annually. Of these, 90 percent, or 99, will seek certification by a certifying board under § 35.290(a). The NRC estimates that the remainder, or approximately 11 physicians, will seek to become authorized users under § 35.290(c).

No significant cost changes are expected.

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety.

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

Existing Regulations

Section 35.390 specifies the training requirements for an authorized user of radiopharmaceuticals for therapeutic administration of unsealed byproduct material.

Section 35.390(a) provides that except as provided in § 35.57, the licensee shall require an authorized user 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 training and experience requirements that may be met in lieu of certification by one of the four listed speciality 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 authorized user to have completed the training and experience specified in § 35.390(b) and to have obtained written certification signed by a preceptor authorized user meeting certain specified requirements; the requirement for a preceptor statement also applies to both the board certification and alternate pathways.

Section 35.390(b)(1) requires completion of 700 hours of training and experience 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 authorized user 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 authorized user status, and lists four categories of administration in §§ 35.390(b)(1)(ii)(G)(*1*) through (G)(*4*).

Proposed Rule Changes

The proposed rule would remove the requirement that the certification pathway includes all of the training and experience requirements in § 35.51(b). The proposed rule would also establish a number of less prescriptive training and experience requirements for the board certification process.

Cost Impacts:

NRC estimates that approximately 100 physicians will seek to become authorized users under § 35.390 or equivalent Agreement State regulations annually. Of these, 95 percent will seek certification by a certifying board under § 35.390(a). Training currently accepted by the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association includes more than 700 hours of classroom and laboratory training and practical experience. The remaining five percent, an estimated four physicians, will seek to become authorized users by satisfying the training and experience requirements in § 35.390(b).

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 Boards by the NRC and Agreement States more efficient. No quantitative estimates of cost savings can be made.

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety. Board certification would be maintained as a viable pathway to meet T&E requirements under 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 training requirements for an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicurie).

Section 35.392(a) provides that, except as provided in § 35.57, the licensee shall require an authorized user 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) 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.

Section 35.392(b) provides that the licensee shall require an authorized user to be an authorized user 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 authorized user to have: (1) successfully completed 80 hours of classroom and laboratory training in specified subjects; (2) work experience under the supervision of an authorized user 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; and (3) obtained written certification, signed by a preceptor authorized user who meets specified requirements, that the individual has successfully completed the classroom and laboratory and work experience requirements and has achieved a level of competency sufficient to function independently as an authorized user for medical uses of unsealed byproduct material using sodium iodide I-131; the requirement for a preceptor statement applies to both the board certification and alternate pathways.

Proposed Rule Changes

The proposed rule would make minor word changes to the requirements.

Cost Impacts:

NRC anticipates no significant costs associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Clarifies regulations.

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 training requirements for an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicurie).

Section 35.394(a) provides that, except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in 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 authorized user to be an authorized user 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 authorized user to have: (1) successfully completed 80 hours of classroom and laboratory training in specified subjects; (2) have work experience under the supervision of an authorized user 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; and (3) have obtained written certification, signed by a preceptor authorized user who meets specified requirements, that the individual has successfully completed the classroom and laboratory and work experience requirements and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300; the requirement for a preceptor statement applies to both the board certification and alternate pathways.

Proposed Rule Changes

The proposed rule would make minor word changes to the requirements.

Cost Impacts:

NRC anticipates no significant costs associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Clarifies regulations.

Training for use of manual brachytherapy sources (§ 35.490).

Existing Regulations

Section 35.490 specifies the training requirements for an authorized user of manual brachytherapy sources.

Section 35.490(a) provides that, except as provided in § 35.57, the licensee shall require an authorized user 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 authorized user 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 authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution involving specified activities; and (3) obtained three years of supervised clinical experience in radiation oncology under an authorized user 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. In addition, the physician must obtain written certification, signed by a preceptor authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in §§ 35.490(b)(1) and (b)(2) 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; the requirement for a preceptor statement applies to both the board certification and alternate pathways.

Proposed Rule Changes

The proposed rule would remove the requirement that the certification pathway include all of the training and experience requirements in § 35.490(b). The proposed rule would also establish a number of less prescriptive training and experience requirements for the certification pathway.

Cost Impacts:

NRC estimates that approximately 150 physicians will seek to become authorized users under § 35.490 or equivalent Agreement State regulations annually. Of these, 95 percent, or 143, will seek certification by a certifying board under § 35.490(a). The NRC estimates that the remainder, or approximately seven physicians, will seek to become authorized users under § 35.490(b).

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 Boards by the NRC and Agreement States more efficient. No quantitative estimates of cost savings can be made.

Health and Safety Impacts:

None anticipated.

Benefits:

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

Training for use of sealed sources for diagnosis (§ 35.590).

Existing Regulations

Section 35.590 specifies the training requirements for an authorized user of sealed sources for diagnosis.

Section 35.590(a) provides that the licensee shall require the authorized user 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 speciality 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.

Proposed Rule Changes

The proposed rule would add an additional requirement to the board certification requirements in paragraph (a) that would require training in the use of the device which an applicant seeks authorization.

Cost Impacts:

No 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 training requirements for the authorized user 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 authorized user of a sealed source for a use listed in § 35.600 to be a physician who is certified by a medical speciality 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 authorized user 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 authorized user 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. The physician also must have obtained written certification that the individual has satisfactorily completed the requirements in §§ 35.690(b)(1) and (b)(2) 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 certification must be signed by a preceptor authorized user who meets the requirements in § 35.690 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.

Proposed Rule Changes

The proposed would rule remove the requirement that the certification pathway include all of the training and experience requirements in § 35.690(b). The proposed rule would establish a number of less prescriptive training and experience requirements for the certification pathway. The proposed rule also adds an additional requirement to the T&E requirements in paragraph (c) that requires training in device operation, safety procedures and clinical use for the types of units which an applicant seeks authorization.

Cost Impacts:

NRC estimates that approximately 150 physicians will seek to become authorized users under § 35.690 or equivalent Agreement State regulations annually. Of these, 95 percent, or 143, seek certification by a certifying board under § 35.690(a). The NRC estimates that the remainder, or approximately seven physicians, seek to become authorized users under § 35.690(b).

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 Boards by the NRC and Agreement States more efficient. No quantitative estimates of cost savings can be made.

Health and Safety Impacts:

None anticipated.

Benefits:

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

SUMMARY OF COST IMPACTS ON LICENSEES

The impacts of the proposed rule should result in some savings from the change to less prescriptive and more flexible requirements for the certification pathway. Applicants are allowed significantly more flexibility in becoming approved through the certification pathway. It is not possible to make quantitative estimates of cost impacts. However, the net result should be cost savings to licensees and applicants.

SUMMARY OF COST IMPACTS ON THE NRC AND AGREEMENT STATES

Costs consist of the NRC/Agreement State staff time needed to assess the boards, and NRC costs to develop the rulemaking. Also, NRC should experience cost savings from avoidance of the need for license amendments.

Costs of Assessing Boards: The cost of assessing Boards 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 0.9 (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 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 authorized user status under NRC regulations. It is beneficial for NRC to maintain the certification pathway.

It is not possible to estimate quantitative cost savings from this action. However, maintaining the certification pathway should result in cost savings. Also, more flexible, less prescriptive T&E requirements for the certification pathway should result in savings to applicants from reductions in unnecessary or duplicative training time and expenses.

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 proposed rule change is estimated at approximately 750 annually[2]. 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 $137,000, the net benefits of the proposed rule appear to be positive.

IMPLEMENTATION

NRC listing of recognized specialty boards will be on the NRC's website, rather than in the regulations. NRC will update the list of recognized boards in a timely manner.

Schedule

NRC's current schedule calls for a proposed rule to be published in the fourth quarter of 2003. Following a public comment period on the proposed rule, a final rule would be published in the 2nd or 3rd quarter of 2004. NRC plans to have the final rule become effective before the expiration of the 2 year transition period for Subpart J — October 24, 2004.

[2] Based on total of all estimated annual applicants under the certification pathway, for each section of Part 35 being changed by the proposed rule.