REGULATORY ANALYSIS

FINAL RULE

10 CFR PART 35 – RECOGNITION OF SPECIALTY BOARDS

BACKGROUND:

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

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

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

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

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

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

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

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

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

DISCUSSION:

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

1. Training and Experience Requirements

Under the regulations in the former 10 CFR Part 35, boards were not required to meet specific didactic/laboratory T&E requirements to attain NRC recognition. Before a board was listed in Subpart J, the ACMUI reviewed its certification program and determined the adequacy of the program. The T&E provisions of the current 10 CFR Part 35, however, specifically mandate that an individual must be certified by a medical specialty board whose certification process requires an individual to meet all the applicable requirements listed in 10 CFR Part 35 for the alternate pathway. This results in situations where the requirements of the board do not match the specific criteria of the current rule.

2. Preceptor Attestation

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

such as the program director. However, this qualified individual need not necessarily be an authorized individual, as required of a preceptor by the final rule.

3. New Types of Use

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

ALTERNATIVES

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

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

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

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

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

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

The regulations add a requirement that licensees submit preceptor statements to the Commission or an Agreement State for each individual being permitted to work as an RSO, AMP, ANP, or AU using the certification pathway. The regulations also specify separate T&E requirements for new types of use, therefore under this option, the concerns regarding the radiation safety for new types of use will be resolved. Option 2 is expected to increase stakeholder confidence because of the avoidance of concerns over potential disruption of

medical services due to a shortage of individuals permitted to work as RSOs, AMPs, ANPs, and AUs.

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

VALUES AND IMPACTS OF THE RULEMAKING

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

Definitions (§ 35.2).

Existing Regulations

Section 35.2 defines various terms.

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

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

Preceptor means an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

Radiation Safety Officer means an individual who --

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

Final Rule Changes

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

Cost Impacts:

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

Health and Safety Impacts:

None anticipated.

Benefits:

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

Information collection requirements: OMB approval (§ 35.8).

Existing Regulations

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

Final Rule Changes

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

Cost Impacts:

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

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

Implementation (§ 35.10).

Existing Regulations

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

Final Rule Changes

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

Cost Impacts:

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

Health and Safety Impacts:

None anticipated.

Benefits:

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

License amendments (§ 35.13).

Existing Regulations

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

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

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

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

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

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

Final Rule Changes

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

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

Cost Impacts:

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

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

Notifications (§ 35.14).

Existing Regulations

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

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

Final Rule Changes

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

Cost Impacts:

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

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

Training for Radiation Safety Officer (§ 35.50).

Existing Regulations

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

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

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

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

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

Final Rule Changes

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

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

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

Cost Impacts:

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

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

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

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

Assumptions:

NRC/Agreement States

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

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

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

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

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

Health and Safety Impacts:

None anticipated.

Benefits:

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

Training for authorized medical physicist (§ 35.51).

Existing Regulations

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

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

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

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

Final Rule Changes

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

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

Cost Impacts:

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

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

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

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

Assumptions:

Licensees

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

NRC/Agreement States

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

Health and Safety Impacts:

None anticipated.

Benefits:

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

Training for an authorized nuclear pharmacist (§ 35.55).

Existing Regulations

Section 35.55 specifies the requirements for an ANP.

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

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

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

Final Rule Changes.

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

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

Cost Impacts:

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

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

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

Assumptions:

Licensees

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

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

NRC/Agreement States

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

Health and Safety Impacts:

None anticipated.

Benefits:

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

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

Existing Regulations

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

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

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

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

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

Final Rule Changes

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

Cost Impacts:

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

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

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

Assumptions:

Licensees

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

NRC/Agreement States

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

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

Health and Safety Impacts:

None anticipated.

Benefits:

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

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

Existing Regulations

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

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

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

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

Final Rule Changes

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

Cost Impacts:

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

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

Training for imaging and localization studies (§ 35.290).

Existing Regulations

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

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

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

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

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

Final Rule Changes

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

Cost Impacts:

The NRC assumes that physicians meeting the T&E requirements to be authorized under § 35.190 will also meet the T&E requirements to be authorized under § 35.290 and therefore anticipates no significant additional costs associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

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

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

Existing Regulations

Section 35.390 specifies the T&E requirements for medical use by an AU of unsealed byproduct material for which a written directive is required.

Section 35.390(a) provides that except as provided in § 35.57, the licensee shall require an AU of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.390(b) and whose certification has been recognized by the Commission or an Agreement State.

Section 35.390(b) specifies T&E requirements that may be met in lieu of certification by one of the four recognized specialty boards. It currently requires 80 hours of classroom and laboratory training in specified subjects. In addition, it requires supervised clinical experience, including use of I-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals and use of I-131 for treatment of thyroid carcinoma in three individuals.

Alternatively, the licensee shall require an AU to have completed the T&E specified in § 35.390(b) and to have obtained written certification, signed by a preceptor AU meeting certain specified requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function

independently as an AU for medical uses authorized under § 35.300. The requirement for a preceptor statement also applies to the board certification pathway.

Section 35.390(b)(1) requires completion of 700 hours of T&E in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. It specifies the topics in which classroom and laboratory training must occur and the areas in which work experience, under the supervision of an AU meeting specified requirements, must occur. Section 35.390(b)(1)(ii)(G) specifies that experience must include administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the categories for which the individual is requesting AU status, and lists four categories of administration in §§ 35.390(b)(1)(ii)(G)(1) through (G)(4).

Final Rule Changes

The final rule removes the requirement that the certification pathway includes all of the T&E requirements in § 35.390(b). Under the final rule, specialty boards are no longer required to require individuals to obtain preceptor statements as part of the board certification process. Specialty boards are no longer required to include the requirements in section 35.390(b)(1)(ii)(G) in their requirements for certification but is retained in requirements for T&E of individuals to qualify under § 35.390. The final rule also establishes a number of less prescriptive T&E requirements for the board certification process and will also add a requirement for a board-administered examination to the certification pathway. A minimum of 200 hours is established for the requirement for classroom and laboratory training in § 35.290(c)(1). The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.390(b)(2).

Cost Impacts:

The NRC estimates that approximately 100 physicians will meet the T&E requirements to become AUs under § 35.390 or equivalent Agreement State regulations annually. Of these, 5 percent, or 5 physicians, will meet the T&E requirements to become AUs under § 35.390(b)and the remaining 95 percent, or 95 physicians, will meet the T&E requirements through certification

by specialty boards that are recognized by the NRC or an Agreement State under the less prescriptive requirements of the final rule.

The NRC anticipates cost savings for licensees, the NRC, and Agreement States from the changes to § 35.390 because the final rule will allow more specialty boards to be recognized by the NRC or an Agreement State which will reduce the need for licensees to apply for and receive license amendments.

Assumptions:

Licensees

Total annual amendments avoided (22 NRC, 73 Agreement States)	95
Physician/management amendment preparation time, hours:	1
Physician/management hourly rate	$100
Technical staff amendment preparation time, hours:	4
Technical staff hourly rate:	$30
Total annual cost savings to licensees	$21,000

NRC/Agreement States

Total annual amendments avoided (22 NRC, 73 Agreement States)	95
Reduction to NRC/Agreement States amendment review time, hours:	3
NRC/Agreement States hourly rate:	$77
Total annual cost savings to NRC and Agreement States	$22,000
Total annual cost savings from changes to § 35.390	$43,000

Health and Safety Impacts:

None anticipated.

Benefits:

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

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

Existing Regulations

Section 35.392 specifies the T&E requirements for an AU for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).

Section 35.392(a) provides that, except as provided in § 35.57, the licensee shall require an AU, for the oral administration of sodium iodide I-131 requiring a written directive for quantities less than or equal to 1.22 gigabecquerels (33 millicuries), to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.392(c) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.392(b) provides that the licensee shall require an AU to be an AU under §§ 35.390(a), 35.390(b), for uses listed in §§ 35.390(b)(1)(ii)(G)(1) or (2), or 35.394 or equivalent Agreement State requirements.

Alternatively, § 35.392(c) provides that the licensee shall require an AU to have successfully completed 80 hours of classroom and laboratory training in specified subjects and to have work experience under the supervision of an AU who meets specified requirements involving specified activities, including administering dosages to patients or human research subjects that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131.

Section 35.392(c) also requires the physician to have obtained written certification , signed by a preceptor AU who meets specified requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an AU for medical uses authorized under § 35.300. The requirement for a preceptor statement also applies to the board certification pathway.

Final Rule Changes

The final rule makes minor word changes to the requirements. The final rule modifies the criteria for approval of board certifications. Under the final rule, specialty boards are no longer required to require individuals to obtain preceptor statements as part of the board certification process. The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.392(c)(3).

Cost Impacts:

The NRC estimates that approximately 100 physicians will meet the T&E requirements to become AUs under § 35.392 or equivalent Agreement State regulations annually. Of these, 10 percent, or 10 physicians, will meet the T&E requirements to become AUs under § 35.392(b) and the remaining 90 percent, or 90 physicians, will meet the T&E requirements through certification by specialty boards that are recognized by the NRC or an Agreement State under the less prescriptive requirements of the final rule.

The NRC anticipates cost savings for licensees, the NRC, and Agreement States from the changes to § 35.392 because the final rule will allow more specialty boards to be recognized by the NRC or an Agreement State which will reduce the need for licensees to apply for and receive license amendments.

Assumptions:

Licensees

Total annual amendments avoided (20 NRC, 70 Agreement States)	90
Physician/management amendment preparation time, hours:	1

Physician/management hourly rate	$100
Technical staff amendment preparation time, hours:	4
Technical staff hourly rate:	$30
Total annual cost savings to licensees	$20,000

NRC/Agreement States

Total annual amendments avoided (20 NRC, 70 Agreement States)	90
Reduction in NRC/Agreement States amendment review time, hours:	3
NRC/Agreement States hourly rate:	$77
Total annual cost savings to NRC and Agreement States	$21,000
Total annual cost savings from changes to § 35.392	$41,000

Health and Safety Impacts:

None anticipated.

Benefits:

Clarifies regulations. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

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

Existing Regulations

Section 35.394 specifies the T&E requirements for an AU for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).

Section 35.394(a) provides that, except as provided in § 35.57, the licensee shall require an AU, for the oral administration of sodium iodide I-131 requiring a written directive for quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.394(c) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.394(b) provides that the licensee shall require an AU to be an AU under § 35.390(a), § 35.390(b) for uses listed in § 35.390(b)(1)(ii)(G)(2), or equivalent Agreement State requirements.

Alternatively, § 35.394(c) provides that the licensee shall require an AU to have successfully completed 80 hours of classroom and laboratory training in specified subjects and to have work experience under the supervision of an AU who meets specified requirements involving specified activities, including administering dosages to patients or human research subjects that includes at least three cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131.

Section 35.394(c) also requires the physician to have obtained written certification , signed by a preceptor AU who meets specified requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an AU for medical uses authorized under § 35.300. The requirement for a preceptor statement also applies to the board certification pathway.

Final Rule Changes

The final rule makes minor word changes to the requirements. The final rule modifies the criteria for approval of board certifications. Under the final rule, specialty boards will no longer be required to require individuals to obtain preceptor statements as part of the board certification process. The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.394(c)(3).

Cost Impacts:

The NRC assumes that physicians meeting the T&E requirements to be authorized under § 35.394 are included in the total under§ 35.392 and therefore anticipates no significant additional costs associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Clarifies regulations. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

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

Existing Regulations
Section 35.390 specifies the T&E requirements for medical use by an AU of unsealed byproduct material for which a written directive is required.

Section 35.390(a) provides that except as provided in § 35.57, the licensee shall require an AU of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.390(b) and whose certification has been recognized by the Commission or an Agreement State.

Section 35.390(b) specifies T&E requirements that may be met in lieu of certification by one of the four recognized specialty boards. It currently requires 80 hours of classroom and laboratory training in specified subjects. In addition, it requires supervised clinical experience, including use of I-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals and use of I-131 for treatment of thyroid carcinoma in three individuals.

Alternatively, the licensee shall require an AU to have completed the T&E specified in § 35.390(b) and to have obtained written certification, signed by a preceptor AU meeting certain specified requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an AU for medical uses authorized under § 35.300. The requirement for a preceptor statement also applies to the board certification pathway.

Section 35.390(b)(1) requires completion of 700 hours of T&E in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. It specifies the topics in which classroom and laboratory training must occur and the areas in which work experience, under the supervision of an AU meeting specified requirements, must occur. Section 35.390(b)(1)(ii)(G) specifies that experience must include administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the categories for which the individual is requesting AU status, and lists four categories of administration in §§ 35.390(b)(1)(ii)(G)(1) through (G)(4).

Final Rule Changes

The final rule creates a new § 35.396 which establishes requirements for T&E for parenteral administration of byproduct material for which a written directive is required. This section was created in response to public comments on the proposed rule that indicated that a certain class of physicians, who now perform these procedures, would not meet the criteria in the current or in the proposed § 35.390. As for other sections in Subpart E, specialty boards will not be required to require individuals to obtain preceptor statements as part of the board certification process. The final rule provides a pathway for becoming a AU for uses of byproduct material under § 35.300, for individuals who may have acquired adequate T&E other than those specified in §§ 35.390 and other sections of Subpart E. The requirements in § 35.396 were modeled after the requirements in other sections of Subpart E and include 80 hours of T&E specific to the use of unsealed sources and experience with at least 3 cases involving parenteral administration of byproduct material for which a WD is required. § 35.396 allows for individuals to take credit for T&E associated with other medical uses of byproduct material that

may be applicable to the uses of unsealed byproduct material, e.g., individuals who are certified by boards who meet the requirements of §§ 35.490 or 35.690 for the use of sealed sources. This new section will provide the flexibility needed to allow individuals, who do not meet other requirements in Subpart E, to serve as AUs for parenteral administration of byproduct material for which a WD is required while ensuring adequacy of T&E for these uses to be safe.

Cost Impacts:

The NRC assumes that physicians meeting the T&E requirements to be authorized under § 35.396 are included in the total under § 35.390 and therefore anticipates no significant additional costs associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35 and will allow individuals who meet similar requirements in Subpart J to meet the requirements in the new rule, increasing regulatory efficiency.

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

Existing Regulations

Section 35.490 specifies the T&E requirements for an AU of manual brachytherapy sources.

Section 35.490(a) provides that, except as provided in § 35.57, the licensee shall require an AU of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who is certified by a medical specialty board whose certification process includes all of the

requirements in § 35.490(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.490(b) provides that the licensee shall require an AU to have: (1) completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes 200 hours of classroom and laboratory training in specified subjects; (2) 500 hours of work experience under the supervision of an AU who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution involving specified activities; and (3) obtained 3 years of supervised clinical experience in radiation oncology under an AU who meets the requirements in § 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience.

Section 35.490(b) also requires the physician to have obtained written certification , signed by a preceptor AU who meets the requirements in § 35.490 or equivalent Agreement State requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an AU of manual brachytherapy sources for the medical uses authorized under § 35.400. The requirement for a preceptor statement also applies to the board certification pathway.

Final Rule Changes

The final rule removes the requirement that the certification pathway includes all of the T&E requirements in § 35.490(b). Under the final rule, specialty boards are no longer required to require individuals to obtain preceptor statements as part of the board certification process. The final rule also establishes a number of less prescriptive T&E requirements for the board certification process and adds a requirement for a board-administered examination to the certification pathway. The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.490(b)(3).

Cost Impacts:

The NRC estimates that approximately 150 physicians will meet the T&E requirements to become AUs under § 35.490 or equivalent Agreement State regulations annually. Of these, 5 percent, or 7 physicians, will meet the T&E requirements to become AUs under § 35.490(b) and the remaining 95 percent, or 143 physicians, will meet the T&E requirements through certification by specialty boards that are recognized by the NRC or an Agreement State under the less prescriptive requirements of the final rule.

The NRC anticipates cost savings for licensees, the NRC, and Agreement States from the changes to § 35.490 because the final rule will allow more specialty boards to be recognized by the NRC or an Agreement State which will reduce the need for licensees to apply for and receive license amendments.

Assumptions:

Licensees

Total annual amendments avoided (33 NRC, 110 Agreement States)	143
Physician/management amendment preparation time, hours:	1
Physician/management hourly rate	$100
Technical staff amendment preparation time, hours:	4
Technical staff hourly rate:	$30
Total annual cost savings to licensees	$31,000

NRC/Agreement States

Total annual amendments avoided (33 NRC, 110 Agreement States)	143
Reduction to NRC/Agreement States amendment review time, hours:	3
NRC/Agreement States hourly rate:	$77
Total annual cost savings to NRC and Agreement States	$33,000
Total annual cost savings from propose to § 35.490	$64,000

Health and Safety Impacts:

None anticipated.

Benefits:

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

Training for ophthalmic use of strontium-90 (§ 35.491).

Existing Regulations

Section 35.491 specifies the T&E requirements for an AU for ophthalmic use of strontium-90.

Section 35.491(b)(3) requires that individuals obtain written certification, signed by a preceptor AU meeting certain specified requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an AU of strontium-90 for ophthalmic use.

Final Rule Changes

The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.491(b)(3).

Cost Impacts:

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

Health and Safety Impacts:

None anticipated.

Benefits:

Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

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

Existing Regulations

Section 35.590 specifies the T&E requirements for an AU of sealed sources for diagnosis.

Section 35.590(a) provides that the licensee shall require the AU of a diagnostic sealed source for use in a device authorized under § 35.500 to be a physician, dentist, or podiatrist who is certified by a specialty board whose certification process includes all of the requirements in § 35.590(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.590(b) requires eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that include: (1) radiation physics and instrumentation; (2) radiation protection; (3) mathematics pertaining to the use and measurement of radioactivity; (4) radiation biology; and (5) training in the use of the device for the uses requested.

Final Rule Changes

The final rule will make minor word changes to the requirements.

Cost Impacts:

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

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

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

Existing Regulations

Section 35.690 specifies the T&E requirements for the AU of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Section 35.690(a) requires that, except as provided in § 35.57, the licensee shall require the AU of a sealed source for a use listed in § 35.600 to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.690(b) and whose certification has been recognized by the Commission or by an Agreement State.

Alternatively, § 35.690(b) provides that the physician must have completed a structured educational program in basic radionuclide techniques, including specified areas of training, applicable to the use of a sealed source in a therapeutic medical unit and must have completed 200 hours of classroom and laboratory training in specified topics and 500 hours of work experience, including specified activities, under the supervision of an AU who meets the requirements in § 35.690 or equivalent Agreement State requirements at a medical institution; and has completed 3 years of supervised clinical experience in radiation oncology, under an AU who meets the requirements in § 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on

Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience.

Section 35.690(b) also requires the physician to have obtained written certification, signed by a preceptor AU, who meets the requirements in § 35.690 or equivalent Agreement State requirements (preceptor statement), that the individual has satisfactorily completed the required T&E and has achieved a level of competency sufficient to function independently as an AU of each type of therapeutic medical unit for which the individual is requesting AU status. The requirement for a preceptor statement also applies to the board certification pathway.

Final Rule Changes

The final rule removes the requirement that the certification pathway includes all of the T&E requirements in § 35.690(b). Under the final rule, specialty boards are no longer be required to require individuals to obtain preceptor statements as part of the board certification process. The final rule also establishes a number of less prescriptive T&E requirements for the board certification process and adds a requirement for a board-administered examination to the certification pathway.

The final rule also adds a requirement to the T&E requirements in § 35.690(d) that requires training in device operation, safety procedures and clinical use for the types of units for which an individual seeks authorization. The word “attestation” is substituted for the word “certification” in the requirements for preceptor statements in § 35.690(b)(3).

Cost Impacts:

The NRC estimates that approximately 150 physicians will meet the T&E requirements to become AUs under § 35.690 or equivalent Agreement State regulations annually. Of these, 5 percent, or 7 physicians, will meet the T&E requirements to become AUs under § 35.690(b) and the remaining 95 percent, or 143 physicians, will meet the T&E requirements through certification by specialty boards that are recognized by the NRC or an Agreement State under the less prescriptive requirements of the final rule.

The NRC anticipates cost savings for licensees, the NRC, and Agreement States from the changes to § 35.690 because the final rule will allow more specialty boards to be recognized by the NRC or an Agreement State which will reduce the need for licensees to apply for and receive license amendments.

Assumptions:

Licensees

Total annual amendments avoided (33 NRC, 110 Agreement States)	143
Physician/management amendment preparation time, hours:	1
Physician/management hourly rate	$100
Technical staff amendment preparation time, hours:	4
Technical staff hourly rate:	$30
Total annual cost savings to licensees	$31,000

NRC/Agreement States

Total annual amendments avoided (33 NRC, 110 Agreement States)	143
Reduction to NRC/Agreement States amendment review time, hours:	3
NRC/Agreement States hourly rate:	$77
Total annual cost savings to NRC and Agreement States	$33,000
Total annual cost savings from changes to § 35.690	$64,000

Health and Safety Impacts:

None anticipated.

Benefits:

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

SUMMARY OF COST IMPACTS ON LICENSEES

The impacts of the final rule should result in some savings from the change to less prescriptive and more flexible requirements for the certification pathway. Individuals are allowed significantly more flexibility in becoming approved through the certification pathway. It is not possible to fully quantify estimates of cost impacts. However, the net result should be cost savings to licensees and individuals exceeding the $147,000 annual savings from the changes to the T&E requirements in 10 CFR Part 35.

SUMMARY OF COST IMPACTS ON THE NRC AND AGREEMENT STATES

Costs consist of the NRC/Agreement State staff time needed to assess the boards' certification processes, and NRC costs to develop the rulemaking. Also, the NRC and Agreement States should experience annual cost savings from the reduced length of time to review license amendments for RSOs and the avoidance of the need for license amendments for AMPs, ANPs, and AUs of approximately $191,000.

Costs of Assessing Board Certification Processes: The cost of assessing specialty boards' certification processes for the purpose of NRC recognition should not change significantly, but any change should result in somewhat lower costs as board requirements are less prescriptive.

Rulemaking Costs: The costs of developing a proposed and final rule to amend T&E requirements in 10 CFR Part 35 are NRC staff time needed. It is estimated that 0.9 full-time equivalent staff years (FTEs) will be required to develop a proposed and final rule. At NRC labor rates of $137K per year, 0.9 FTEs is $123K.

PREFERRED ALTERNATIVE AND DECISION RATIONALE

The preferred alternative is to implement a rulemaking to amend requirements for T&E in 10 CFR Part 35.

The action is in keeping with a more performance-based, less prescriptive 10 CFR Part 35. This action should enhance regulatory efficiency by bringing NRC regulations more in accordance with the certification procedures of the medical specialty boards. The medical specialty boards provide a valuable service by maintaining a pathway for applicants to obtain AU status under NRC regulations. It is beneficial for the NRC to maintain the certification pathway.

It is not possible to fully estimate quantitative cost savings from this action. However, maintaining the certification pathway should result in cost savings in excess of the $338,000 resulting from the changes to the T&E requirements in 10 CFR Part 35. Also, more flexible, less prescriptive T&E requirements for the certification pathway should result in savings to applicants.

While cost savings to individuals may not be substantial, total cost savings for all applicants using the certification pathway could be substantial. The total number of applicants for all types of use covered by the final rule change is estimated at approximately 820 annually[4]. Even assuming individual cost savings for each applicant were small, annual total savings could be substantial. Compared to the cost of the action, an estimated $123,000, the quantitative net benefits of the final rule alone are positive.

IMPLEMENTATION

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

Schedule

The NRC final rule becomes effective 30 days after publication in the Federal Register. Requirements in Subpart J will remain in effect for an additional year beyond the 2-year transition period for Subpart J, that is, until October 24, 2005. The action is being effected by a

[4]Based on total of all estimated annual applicants under the certification pathway, for each section of 10 CFR Part 35 being changed by the final rule.

separate rulemaking (69 FR 55736, September 16, 2004)). This is an additional year beyond that assumed when cost estimates were prepared for the proposed rule. Difference in estimated costs due to this difference in time are negligibly small.