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.