Proposed Rules

Federal Register
Vol. 68, No. 236
Tuesday, December 9, 2003

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150–AH19

Medical Use of Byproduct Material—Recognition of Specialty Boards

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the medical use of byproduct material to change its requirements for recognition of specialty boards whose certifications may be used to demonstrate the adequacy of the training and experience of individuals to serve as radiation safety officers, authorized medical physicists, authorized nuclear pharmacists or authorized users. The proposed rule would also revise the requirements for demonstrating the adequacy of training and experience for pathways other than the board certification pathway. This rulemaking is necessary to address the training and experience issue for recognition of specialty board certifications.

DATES: The comment period expires February 23, 2004. Comments received after this date will be considered if it is practical to do so, but the NRC can only assure consideration for comments received on or before this date.

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

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

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

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. on Federal workdays (telephone (301) 415–1966).

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

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

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/NRC/ADAMS/index.html.* From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1–800–397–4209, 301–415–4737 or by e-mail to *pdr@nrc.gov.*

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

SUPPLEMENTARY INFORMATION:

Background

During development of 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 NRC. However, when applications for recognition were received, the NRC staff determined that, except for one board, the boards did not meet all the requirements specified in the final rule. Specifically, the boards' certification programs failed to meet the requirements in the final rule regarding preceptor certification and work experience. The only board that currently meets the revised requirements is the Certification Board of Nuclear Cardiology (CBNC) because it developed its certification program based on the final rule. The NRC staff held several discussions with the boards to determine whether the boards would modify their certification processes to meet all the requirements specified in the rule. With the exception of the CBNC, no board indicated that it would modify its certification process.

The current regulations in 10 CFR part 35 offer three pathways for individuals to satisfy training and experience (T&E) requirements to be approved as a radiation safety officer (RSO), authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), or authorized user (AU). These pathways are: (1) Approval of an individual who is certified by a specialty board whose certification has been recognized by the NRC or an Agreement State as meeting the NRC's requirements for training and experience (a ''recognized board''); (2) approval based on an evaluation of an individual's training and experience; or (3) identification of an individual's approval on an existing NRC or Agreement State license. For the sake of this discussion, pathway (1) will be referred to as the certification pathway, and pathway (2) as the alternate pathway. For example, in § 35.50, the proposed criteria for meeting training and experience requirements for the certification pathway (1) appear in § 35.50(a); those for the alternate pathway (2) appear in § 35.50(b); and those for pathway (3) appear in § 35.50(c).

On February 19, 2002, in a briefing of the Commission, the Advisory

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

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

Based on these concerns, the ACMUI urged the Commission to implement measures to address the training and experience issues associated with recognition of specialty boards by the NRC in the draft final rule and to find a permanent solution after publication of the final rule. Subsequently, the NRC modified the final rule by reinserting subpart J (as contained in the proposed rule) for a 2-year transition period. Subpart J provides for continuing recognition of the specialty boards listed therein during the transition period. The final rule was published in the **Federal Register** on April 24, 2002 (67 FR 20249), and became effective on October 24, 2002. As specified in § 35.10(c), the 2-year transition period ends on October 24, 2004. In a Staff Requirements Memorandum (SRM–COMSECY–02–0014) dated April 16, 2002, the Commission directed the NRC staff to develop options for addressing the training and experience issue. The intent is to have this new rule in place before the end of the 2-year transition period.

The issue in question concerns the requirements in the rule governing the recognition of specialty boards by the NRC. These requirements are located in the current regulations at 10 CFR 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590, and 35.690.

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

The ACMUI full committee discussed the subcommittee's recommendations in a public teleconference meeting on July 8, 2002. Members of the public and representatives from the Society of Nuclear Medicine participated in the teleconference. The ACMUI approved the recommendations of the subcommittee and submitted them in a report to the NRC on August 1, 2002. The report provided a rationale for the recommendations accompanied by suggested rule language. The NRC staff presented three options to the Commission in a Commission paper, SECY–02–0194, dated October 30, 2002, which included the recommendations of the ACMUI at Attachment 2. The three options were: Option (1) retain the existing requirements in the current regulations; Option (2) prepare a proposed rule to modify training and experience requirements based on the recommendations submitted by the ACMUI; and, Option (3) the same as Option 2 with a minor modification (*i.e.*, listing all specialty boards recognized by NRC on the NRC's Web site rather than, as recommended by the ACMUI, listing some boards in the regulation and others on the Web site).

In SRM–02–0194 dated February 12, 2003, the Commission approved Option 3, directing the NRC staff to prepare a proposed rule based on the ACMUI's recommendations with certain exceptions. Current regulations in 10 CFR part 35 require that individuals obtain a written certification that they have satisfactorily completed requirements for T&E and have achieved a level of competency sufficient to function independently (*see, e.g.*, § 35.50(b)(2)). For the sake of discussion, this certification will be referred to herein as a preceptor statement. (The term ''preceptor'' is defined in § 35.2.) The Commission directed that a list of recognized boards be posted on the NRC's web site, that the preceptor statement remain as written in the current regulations (published April 24, 2002), and that the staff should clarify that the preceptor language does not require an attestation of general clinical competency, but does require sufficient attestation to demonstrate that the candidate has the knowledge to fulfill the duties of the position for which certification is sought. This form of attestation should be preserved both for the certification pathway and the alternate pathway.

The ACMUI briefed the Commission on May 28, 2003, and members conveyed their views regarding the Commission's direction to NRC staff, relating to preceptor statements, in SRM–02–0194. The Commission subsequently issued an SRM on June 20, 2003 (SRM–M030528B). This SRM directed that the staff continue its development of a proposed rule to modify the training and experience requirements in 10 CFR part 35, with appropriate interactions with the ACMUI, so that the revised rule can be in place as promptly as possible. The NRC staff met with the ACMUI via teleconference on July 17, 2003, to further discuss the ACMUI's comments on the proposed rule. This meeting was noticed in the **Federal Register** on July 14, 2003 (68 FR 41665).

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

still believed it necessary to include a preceptor statement for all ''authorized positions'' named in 10 CFR part 35, the ACMUI recommended that this requirement be separated from the board certification pathway and that it be specified separately as a new paragraph in each training section. In SRM–03–0145, issued on October 9, 2003, the Commission approved the recommendation of the ACMUI that the requirement for a preceptor statement be removed from the requirements for recognition of specialty board certifications. The Commission also indicated it should be clear in the proposed rule language that a preceptor statement is required regardless of which training pathway is chosen.

Discussion

The principal changes proposed to 10 CFR part 35 involve revising the criteria for recognizing the certifications of specialty boards. These changes relate to the requirements for training and experience (T&E) that boards would place on candidates seeking board certification. The NRC staff reviewed board certification procedures and made a determination that, with one exception, the boards' certification programs failed to meet the requirements in the current regulations regarding preceptor certification and work experience. This assessment [1] resulted from a detailed comparison, performed by the NRC staff, between requirements in the regulations (in subparts D–H) and specialty board requirements for certification. The changes resulting from adoption of the proposed rule would remedy this situation and result in requirements that are less prescriptive while maintaining public health and safety. These changes would ensure that a clear regulatory determination can be made that specialty boards, both new and existing, meet the relevant criteria for recognition by the NRC or an Agreement State. Minor changes would also be made to the training and experience requirements in the alternate pathway.

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

The NRC is seeking public comment on specific issues related to this proposed rule (*see* the section entitled ''*Invitation for Public Comment on Specific Issues,*'' below).

Changes to the Certification Pathway

For the certification pathway, the current regulations incorporate the more prescriptive requirements for the alternate pathway. The proposed rule would establish criteria for a board to be recognized by the NRC or an Agreement State.

For the RSO, AMP, and ANP, the proposed criteria include a degree from an accredited college or university, professional experience, passing an examination administered by the board, and in some cases additional training related to the type of use for which an individual would be responsible. The requirement for passing an examination reflects the current practice of certification boards.

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

The requirement that boards must have candidates for certification obtain a preceptor statement as a condition for NRC recognition of certifications would be removed in the proposed rule; however, individuals would still be required to obtain preceptor statements and licensees would be required to submit them to the NRC (broad scope, type A licensees would be exempt from this requirement as provided under § 35.15(d)). This would be an addition to the current requirement in § 35.14(a) to provide a copy of board certifications to the NRC. Further discussion of the requirement for a preceptor statement appears below under the heading ''*Preceptor Certification*.'' The certification pathway also includes a specification for the number of hours of training and experience for ANPs and AUs for certain uses of byproduct material under §§ 35.100, 35.200, 35.300 (in 35.390, 35.392, 35.394 for uses under 35.300), and 35.500. The ACMUI recommended that the requirement for 200 hours of classroom and laboratory training, now required in §§ 35.490 and 35.690, be removed because it believes that the combination of degree, practical experience, and examination in the criteria for recognizing certifying boards is equivalent to the number of hours of didactic training and experience specified for the alternative pathway. A detailed analysis of T&E requirements was performed by NRC staff and appears as Attachment 1 to SECY–02–0194. This assessment included a comparison of the number of hours of training required both for the board certification and alternate pathway, with estimates of the equivalency of hours of T&E leading to board certification in comparison to the hours required under the alternate pathway. The NRC believes that, although the requirements are not identical, the T&E standard for recognizing certifying boards would be equivalent to the standard for the alternate pathway. The board certification process requires a

[1] ''Comparison Between NRC Requirements and Boards Certification Programs,'' Attachment 2 to SECY–02–0194, ''Options for Addressing part 35 Training and Experience Issues Associated with Recognition of Specialty Boards by NRC.'' SECY–02–0194 is available on the NRC's Web site, *http://www.nrc.gov,* in the ''Electronic Reading Room.''

candidate to have an academic degree, complete practical experience or a residency program, and pass an examination. Examinations test the knowledge and skills required to perform the applicable activities, including those in proposed §§ 35.490(a)(2) and 35.690(a)(2), to ensure radiation safety. The NRC believes that the combination of a degree, practical experience and an examination in the proposed criteria for recognizing certifying boards would be equivalent to the number of hours of didactic training and experience specified for the alternate pathway. Further, the proposed requirement in the certification pathway for §§ 35.390, 35.490 and 35.690 for completion of an approved, 3-year residency program provides added assurance that T&E is sufficient.

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

The proposed rule would provide the boards more latitude in making the determination that individuals are fully trained and capable of performing their duties involving radiation safety. These proposed changes to the certification pathway would continue to ensure the safe use of byproduct material by medical licensees by establishing criteria for specialty boards to use in granting certifications. The NRC made a determination that, with the exception of one specialty board, the boards do not meet the requirement in the current rule regarding preceptor certification and work experience. The proposed revisions for the certification pathway would remedy the problem of boards not meeting current requirements in 10 CFR part 35.

Changes to the Alternate Pathway

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

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

Training Specific to Type of Use

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

Other Changes

In the current rule, § 35.390(b)(1) specifies that work experience for uses of byproduct material in unsealed form for which a written directive is required must include administering dosages of radioactive drugs involving a minimum of three cases in each of the categories for which the individual is requesting authorized user status. Sections 35.390(b)(1)(ii)(G)(*3*) and (*4*) refer to parenteral administration of certain radionuclides. The proposed rule would clarify that this training must be with quantities of radionuclides for which a written directive is required. The NRC supports these changes because, without them, an individual might cite experience with low-level dosages to satisfy requirements for work experience; the changes place emphasis on the need for AUs to have work experience with higher level dosages, for which a written directive is required.

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

Training requirements for authorizations as a medical physicist would be changed in § 35.51(b)(1) to remove specific requirements for a degree in biophysics, radiological physics, and health physics, and add the more general, other physical sciences, as well as engineering and applied mathematics. The requirement for 1 year of full-time training in therapeutic radiological physics would be changed to a more general requirement for 1 year of full-time training in medical physics. Similarly, the requirement for training in a clinical radiation oncology facility would be changed to a requirement for training in ''clinical radiation facilities.'' Pluralizing ''facility'' makes it possible for candidates to receive training in more than one institution. In § 35.690(b)(2), the requirement for candidates to be approved as AUs would be changed to broaden the requirement that supervised clinical experience be received in ''radiation therapy'' rather than in ''radiation oncology.'' These changes are needed to allow for the therapeutic use of byproduct material in applications other than cancer therapy and allowing for T&E to be obtained in more than one facility.

Current regulations in § 35.50(c) provide that an AMP identified on a licensee's license can serve as an RSO, provided that the individual has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has responsibilities as an RSO. However, current regulations only require services of an AMP for uses under §§ 35.433 and 35.600; a few AMPs are also named on licenses for uses under § 35.1000. Therefore, individuals who may have adequate T&E to serve as AMPs for types of use licensed under §§ 35.100, 35.200, 35.300, 35.400 and 35.500, are not listed on an NRC or Agreement State license under current rules. Medical physicists who are certified by a specialty board recognized by the Commission or an

Agreement State have training and experience in radiation safety aspects of the use of byproduct material for medical purposes. A change to the regulations in § 35.50(c) is proposed that would allow medical physicists, who are certified by a specialty board recognized by the NRC or an Agreement State, to serve as RSOs, while retaining the requirement that such individuals have experience specific to the types of use for which they would be responsible. This change would remove an impediment for individuals who have adequate T&E to become approved as RSOs. It would also avoid placing a burden on licensees to apply for an exemption to regulations and on NRC and Agreement State staff who would be required to process an application for an exemption to regulations in order to approve a licensee's request to have a medical physicist, certified by a recognized specialty board, serve as an RSO.

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

Preceptor Certification

10 CFR part 35 currently requires a written certification that the individual has satisfactorily completed the required training and has achieved a level of knowledge or competency sufficient to function independently and requires that the written certification be signed by a preceptor who is a radiation safety officer, authorized medical physicist, authorized nuclear pharmacist or authorized user. This requirement applies to both the board certification and alternate pathways.

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

As explained above, the Commission considered recommendations of the ACMUI and determined in SRM–02–0194 that the preceptor statement should remain as written in the current regulations. However, the Commission emphasized that the preceptor language does not require an attestation of general clinical competency, but requires sufficient attestation to demonstrate that the candidate has the knowledge to fulfill the duties of the position for which certification is sought.

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

The requirement for licensees to submit a preceptor statement to the NRC appears in the proposed rule in § 35.14(a). Conforming changes are proposed for definitions of RSO, AMP, ANP, and AU in § 35.2 to include the references to a requirement for preceptor statements. Conforming changes are also proposed to include appropriate references to the requirement for a preceptor statement in §§ 35.13(b)(1), 35.13(b)(2), and 35.13(b)(3).

Listing of Recognized Boards

The NRC would list on its Web site, instead of in its regulations, the names of boards whose certification process meets the NRC's criteria. This approach has the advantage of eliminating the need to amend 10 CFR part 35 to effect recognition each time a new board needs to be added to the listing. The ACMUI and specialty board representatives who participated in a public meeting on May 20, 2003, were in agreement with this approach.

Boards that are currently listed in subpart J of part 35 and other boards would be required to apply for recognition under this rule. NRC staff will review a board's submittal with the ACMUI before a decision on recognition of a board is made.

The NRC plans to place the procedures for listing and delisting of specialty boards on its Web site before the effective date of the final rule, if adopted. Because of the important role of board certification, the procedures will provide for making a clear regulatory determination that boards, both new and existing, meet the relevant criteria in the revised regulations. The procedures will provide for both adding new specialty boards to the recognized listing and for removing boards from the recognized list.

The NRC staff does not intend to conduct inspections of the recognized specialty boards, but will monitor trends in medical events. If the NRC staff determines that a series of medical events is associated with a particular specialty and the trend can be attributed to inadequate radiation safety training, the staff will determine whether the inadequate training is related to a board's requirements for radiation safety training. If this is the case, the NRC staff will review the specialty board's certification program. The assessment will include a determination of whether the board's examination adequately assesses the requisite knowledge and skills. If the staff determines that changes in the board's requirements for training in radiation safety are necessary and the board either cannot or will not make adequate changes to its training program to address these needs, then the NRC will withdraw recognition of that specialty board's certification and delist that board. The NRC staff will consult with the ACMUI regarding such actions and will inform the Commission of an NRC staff decision to withdraw recognition. The NRC has reviewed existing procedures for the conduct of inspections and has determined that they provide for collection of the information necessary to evaluate trends in medical events possibly related to requirements for T&E of specialty boards.

Stakeholder Interactions

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

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

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

Additional Recommendations of the ACMUI

At the teleconference held on July 17, 2003, the full ACMUI discussed the draft proposed rule. During the teleconference, the ACMUI approved the NRC staff recommendation to broaden the requirement that supervised clinical experience be received in a ''radiation facility'' rather than in a ''radiation oncology facility'' for individuals to qualify as AMPs, in § 35.51(b)(1) of the proposed rule, and to change the requirement for experience in ''radiation oncology'' in paragraph § 35.690(b)(2) to allow for experience in ''radiation therapy.'' Parallel changes were made to the certification pathway for AMPs in the proposed rule in § 35.51(a)(2)(ii) and in § 35.690(a)(1) for uses under § 35.600. Secondly, the ACMUI recommended that the requirements for experience, described in the current rule in § 35.390(b)(1)(ii)(G), not be included in criteria for recognition of specialty board certifications, but, that they continue to be required for AUs meeting T&E requirements for both the certification and alternate pathways. This recommendation was not adopted because the NRC staff believes that the requirements for work experience in § 35.390(b)(1)(ii)(G) are essential for an individual to be able to function independently as an AU for administration of byproduct material for which a written directive is required. Furthermore, if the requirement were removed from the certification pathway, individuals and applicants for licenses or amendments would be required to provide documentation of completion of requirements for experience required under § 35.390(b)(1)(ii)(G), in addition to evidence of board certification, to gain approval as AUs. Therefore, this requirement was retained in the proposed rule. Thirdly, the ACMUI recommended that the requirement for a preceptor statement be separated from the board certification pathway and the alternate pathway, and specified separately as a new paragraph in each training section. This recommendation was approved by the Commission in SRM–03–0145 and incorporated into the proposed rule. Lastly, the ACMUI recommended that the word ''attest'' should be used in place of certify (certification) in preceptor statements. The ACMUI explained that the reason for this recommendation was to reflect the current practice that preceptors do not ''certify'' individuals, but ''attest.'' As noted below under the heading ''*Invitation for Public Comment on Specific Issues,*'' the NRC is inviting comment on the issue of whether the word ''attestation'' should be used in place of the word ''certification'' in preceptor statements.

Timing of Agreement State Implementation

Normally, Agreement States have 3 years in which to adopt a compatible rule. Agreement States have until October 24, 2005, to adopt the revised 10 CFR part 35 published on April 24, 2002. For Agreement States to adopt the proposed training and experience requirements contained in this proposed rule and have them in place by October 24, 2005, the Agreement States would have a shortened time frame for developing compatible requirements. Agreement States have voiced concern regarding this shortened time frame. As indicated below under the heading ''*Invitation for Public Comment on Specific Issues,*'' the NRC is inviting comment on the timing of implementation of the proposed rule in Agreement States.

Invitation for Public Comment on Specific Issues.

The NRC is seeking public comment on the following issues:

1. Do the proposed revisions to requirements for training and experience provide reasonable assurance that RSOs, AMPs, ANPs, and AUs will have adequate training in radiation safety?

2. Should Agreement States establish the requirements to conform with this proposed rule by October 24, 2005, or should they follow the normal process and be given a full 3 years to develop a compatible rule? (*See* discussion under the heading, ''Timing of Agreement State Implementation,'' above.)

3. Should the word ''attestation'' be used in place of the word ''certification'' in preceptor statements? (*See* discussion under the topic ''*Recommendations of the ACMUI,*'' above.)

Section-by-Section Analysis

Section 35.2—Definitions

This section would be amended to incorporate conforming changes necessitated by amendments to other sections. The definition of authorized medical physicist (AMP) would be changed to include a reference in paragraph (1) to the requirement for obtaining a preceptor statement in proposed § 35.51(c) and the proposed requirement for training specific to type of use in proposed § 35.51(d). The definition for authorized nuclear pharmacist (ANP) would be changed in paragraph (1) to include a reference to the requirement for obtaining a preceptor statement in proposed § 35.55(c). The definition of authorized user (AU) would be changed in paragraph (1) to include references to the requirement for obtaining a preceptor statement in proposed §§ 35.390(c), 35.490(c), and 35.690(c). The requirement for training specific to type of use in proposed § 35.690(d) would also be added to the definition of AU. The definition of radiation safety officer (RSO) would be changed in paragraph (1) to include references to the requirements for obtaining a preceptor statement in proposed § 35.50(c) and 35.50(d)(ii) and to the requirement for training specific to type of use in proposed § 35.50(e).

Section 35.10—Implementation

This section would be amended to incorporate conforming changes necessitated by amendments to other sections. Paragraph (b) would be amended to require implementation of §§ 35.50(c), 35.50(e), 35.51(c), 35.51(d), 35.55(c), 35.390(c), 35.490(c), 35.690(c) and 35.690(d) by the effective date of the regulation.

Section 35.13—License Amendments

Paragraphs (b)(1), (b)(2), and (b)(3) of this section would be amended conform with changes to § 35.14(a) and proposed addition of §§ 35.390(c), 35.490(c), and 35.690(c) which would require submission of preceptor statements to the NRC. Paragraphs (b)(1) and (b)(3) would be amended to reference requirements for T&E specific for types of use added in proposed amendments § 35.690(d) and § 35.51(d), respectively.

Section 35.14—Notifications

This section would be amended to add a requirement to paragraph (a) to submit a copy of a written certification signed by a preceptor in addition to a copy of the board certification now required in this paragraph.

Section 35.50—Training for Radiation Safety Officer

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

Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway (§ 35.50(b) in the current rule), paragraph (a) would be amended to provide separate requirements for a specialty board's certification process. This process would include a requirement to pass an examination, administered by diplomates of the specialty board, which would evaluate knowledge and competency areas that are important to functioning as an RSO. Requirements for training would be changed to add requirements for a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science, and 5 years of professional experience in health physics, including at least 3 years in applied health physics (graduate training could be substituted for up to 2 years of experience). Paragraph (a) would also be amended to include a statement that recognized board certifications will be posted on the NRC's Web page. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications. This requirement, now in paragraph (b)(2), would be moved to paragraph (c) and apply to both the certification and alternate pathway. A new paragraph (d)(2)(i) would be added to allow medical physicists to serve as RSOs if they are certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State, with the requirement for a preceptor statement included in paragraph (d)(2)(ii). A new paragraph (e) would be added to require training in radiation safety, regulatory issues, and emergency procedures for the types of use for which an applicant seeks authorization. Paragraph (e) would apply to all pathways.

Section 35.51—Training for an Authorized Medical Physicist

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

Section 35.55—Training for an Authorized Nuclear Pharmacist

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would be amended to provide separate requirements for a specialty board's certification process. This certification process would include a requirement to pass an examination, administered by diplomates of the specialty board, which would evaluate knowledge and competency areas that are important to functioning as an ANP. Paragraph (a) would also be amended to include a statement that recognized board certifications will be posted on the NRC's Web page. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an AMP; the requirement would be moved from paragraph (b)(2) to a new paragraph (c).

Section 35.57—Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist

Paragraphs (a) and (b) would be amended to change ''October 24, 2002,'' to the effective date of the final rule, if adopted.

Section 35.190—Training for Uptake, Dilution, and Excretion Studies

Paragraph (a) would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under § 35.190. A requirement would be added that candidates must pass an examination administered by diplomates of the specialty board. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an AU under § 35.100. Paragraph (a) would also be amended to include a statement that recognized board certifications will be posted on the NRC's Web page. Paragraph (c)(1)(ii)(B) would be amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments.

Section 35.290—Training for Imaging and Localization Studies

Paragraph (a) would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under § 35.290. A requirement would be added that candidates must pass an examination, administered by diplomates of the specialty board. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an AU under § 35.200. Paragraph (a) would also be amended to include a statement that recognized board certifications will be posted on the NRC's Web page. Paragraph (c)(1)(ii)(B) would be amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the

activity of dosages, a change from requiring only the calibration of these instruments.

Section 35.390—Training for Use of Unsealed Byproduct Material for Which a Written Directive Is Required

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under § 35.390. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would be amended to provide separate requirements for a specialty board's certification process. The training and experience required for the certification pathway would be changed to include, in § 35.390(a)(1), a requirement that individuals complete 3 years of residency training in a radiation therapy, nuclear medicine or a related medical specialty training program approved by the Residency Review Committee of the Accreditation Council for Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association. Paragraph (a) would also be amended to include a statement that recognized board certifications will be posted on the NRC's Web page. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an AU under § 35.390. The requirement for a preceptor statement would be moved from paragraph (b)(2) to a new paragraph (c). Paragraph (b)(1)(ii)(B) would be amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments. In addition, paragraphs (b)(1)(ii)(G)(*3*) and (*4*) would be amended to revise requirements for work experience involving parenteral administration of dosages, clarifying them to indicate that the experience is to be with cases for which written directives are required.

Section 35.392—Training for the Oral Administration of Sodium Iodide I–131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicuries)

Paragraph (a) would be amended to include a statement that recognized board certifications will be posted on the NRC's Web page. Paragraph (c)(2)(ii) would be amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an AU under § 35.392. The requirement for a preceptor statement would be moved from paragraph (c)(3) to a new paragraph (d).

Section 35.394—Training for the Oral Administration of Sodium Iodide I–131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries)

Paragraph (a) would be amended to include a statement that recognized board certifications will be posted on the NRC's Web page. Paragraph (c)(2)(ii) would be amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an AU under § 35.392. The requirement for a preceptor statement would be moved from paragraph (c)(3) to a new paragraph (d).

Section 35.490—Training for Use in Manual Brachytherapy Sources

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would provide separate requirements for a specialty board's certification process. The training and experience required for the certification pathway would be changed to include, in § 35.490(a)(1), a requirement that individuals complete 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association. Paragraph (a) would also be amended to include a statement that recognized board certifications will be posted on the NRC's Web page. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an AU under § 35.490. Additionally, paragraph (b)(2) would be amended to include the Royal College of Physicians and Surgeons of Canada in the listing of organizations that can provide approval of the formal training program.

Section 35.590—Training for Use of Sealed Sources for Diagnosis

Paragraph (a) would be amended to include a statement that recognized boards would be posted on the NRC's Web page. Paragraph (b)(5) would be redesignated as paragraph (c) and would apply to both the certification and the alternate pathways. This revision would separate the requirement for training in the use of the device for the uses requested from the requirement for 8 hours of classroom and laboratory training in basic radionuclide handling techniques.

Section 35.690—Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under 35.600. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would be amended to provide separate requirements for a specialty board's certification process. Paragraph (a) would also be amended to include a statement that recognized board certifications will be posted on the NRC's web page. The training and experience required for the certification pathway would be changed to include, in § 35.690(a)(1), a requirement that individuals complete 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead,

apply to each individual seeking recognition as an AU under § 35.690. Additionally, for the alternate pathway, paragraph (b)(2) would be amended to include the Royal College of Physicians and Surgeons of Canada in the listing of organizations that can provide approval of the formal training program. The requirement for experience in ''radiation oncology'' in paragraph (b)(2) would be modified to allow for experience in ''radiation therapy.'' A new paragraph (c) would be added to require training in device operation, safety procedures, and clinical use for the type(s) of use for which approval as an AU is sought. Paragraph (c) would apply to all pathways.

Agreement State Compatibility

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), this proposed rule would be a matter of compatibility between NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. The Compatibility Categories for the sections amended in this proposed rule would be the same as for the sections in the current regulations. The revisions to §§ 35.2, 35.10, 35.13, 35.14, 35.50, 35.51, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590, and 35.690 are classified as Compatibility Category B. A Compatibility Category ''B'' designation means the requirement has significant direct transboundary implications. Compatibility Category ''B'' designated Agreement State requirements should be essentially identical to those of NRC.

Plain Language

The Presidential Memorandum dated June 1, 1998, entitled, ''Plain Language in Government Writing'' directed that the Government's writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31883). The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the heading **ADDRESSES** above.

Voluntary Consensus Standards

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

Finding of No Significant Environmental Impact: Environmental Assessment

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

Introduction

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

The Proposed Action

The proposed action under consideration is an amendment to the Commission's regulations governing the medical use of byproduct materials (10 CFR part 35). The proposed action would change the requirements for recognition of specialty boards whose certification may be used to demonstrate the adequacy of the training and experience of individuals to serve as an RSO, AMP, ANP, or AU. The proposed action would also amend certain requirements for the training and experience of individuals who do not choose the board certification pathway.

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

Need for the Proposed Action

This rulemaking is needed to address the training and experience issue for recognition of certifications of specialty boards by the NRC for approval of individuals to serve as RSOs, AMPs, ANPs or AUs. Without this rulemaking, the issue of board recognition would not be addressed. Subpart J expires on October 24, 2004, and without this rulemaking, there could be a potential shortage of individuals authorized to perform medical procedures involving the use of byproduct material.

Alternatives to the Proposed Action

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

Environmental Impacts of the Proposed Action

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

knowledge and experience that is integral to radiation safety. The proposed amendments to 10 CFR part 35 are expected to have no significant impact on the public health and safety, occupational health and safety, and the environment.

Agencies and Persons Consulted and Sources Used

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

Finding of No Significant Impact

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

The determination of this environmental assessment is that there will be no significant impact to the public from this action. However, the general public should note that the NRC seeks public participation. Comments on any aspect of the Environmental Assessment may be submitted to the NRC as indicated under the **ADDRESSES** heading.

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

Paperwork Reduction Act Statement

This rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

The burden to the public for these information collections is estimated to average 1.4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden, to the Records and FOIA/Privacy Services Branch (T5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by Internet electronic mail at *infocollects@nrc.gov;* and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202, (3150–0010 and 3150–0120), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by January 8, 2004. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

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

Regulatory Analysis

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

The Commission requests public comment on the draft regulatory analysis. Comments on the analysis may be submitted to the NRC as indicated under the **ADDRESSES** heading. The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Public File Area O1 F21, Rockville, Maryland. Single copies of the draft regulatory analysis are available from Roger W. Broseus, Office of Nuclear Material Safety and Safeguards, telephone (301) 415–7608, e-mail *rwb@nrc.gov.*

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the medical use of byproduct material to change its requirements for recognition of specialty boards whose certification may be used to demonstrate the adequacy of the training and experience of individuals to serve as radiation safety officers, authorized medical physicists, authorized nuclear pharmacists or authorized users. The proposed rule would also revise the requirements for demonstrating the adequacy of training and experience of individuals who do not choose pathways other than the board certification pathway. The regulatory flexibility analysis prepared for the final rule on part 35 (67 FR 20249; April 24, 2002) indicated that about 740 out of 1688 licensees could be considered small entities. The proposed rule should have no burden or economic impact on licensees because it does not add new requirements; it would provide a revision to an existing option.

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

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

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

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

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

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

Backfit Analysis

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

List of Subjects in 10 CFR Part 35

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

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

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

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

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

2. In § 35.2, the definitions of ''authorized medical physicist,'' ''authorized nuclear pharmacist,'' ''authorized user,'' and ''radiation safety officer'' are amended by republishing the introductory text and revising paragraph (1) of each definition to read as follows:

§ 35.2 Definitions.

* * * * *

Authorized medical physicist means an individual who—

(1) Meets the requirements in §§ 35.51(a), 35.51(c), 35.51(d), and 35.59; or, before October 24, 2004, meets the requirements in §§ 35.961(a), or (b), and 35.59; or

* * * * *

Authorized nuclear pharmacist means a pharmacist who—

(1) Meets the requirements in §§ 35.55(a), 35.55(c) or 35.55(d)(2), 35.55(e), and 35.59; or, before October 24, 2004, meets the requirements in §§ 35.980(a) and 35.59; or

* * * * *

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) and (c), 35.392(a), 35.394(a), 35.490(a) and (c), 35.590(a), or 35.690(a), 35.690(c) and 35.690(d); or, before October 24, 2004, meets the requirements in §§ 35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.950(a), 35.960(a) and 35.59; or

* * * * *

Radiation Safety Officer means an individual who—

(1) Meets the requirements in §§ 35.50(a), 35.50(c), 35.50(e), and 35.59; or 35.50(d), 35.50(e), and 35.59; or, before October 24, 2004, §§ 35.900(a) and 35.59; or

* * * * *

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

§ 35.10 Implementation.

* * * * *

(b) A licensee shall implement the training requirements in §§ 35.50(a), 35.50(c), 35.50(e), 35.51(a), 35.51(b), 35.51(c), 35.51(d), 35.55(a), 35.55(c), 35.59, 35.190(a), 35.190(c), 35.290(a), 35.290(c), 35.390(a), 35.390(b), 35.390(c), 35.392(a), 35.392(c), 35.394(a), 35.394(c), 35.490(a), 35.490(b), 35.490(c), 35.590(a), 35.590(b), 35.690(a), 35.690(b), 35.690(c), and 35.690(d) on or before ''[insert effective date of final rule]''.

* * * * *

4. In § 35.13, paragraphs (b)(1), (b)(2) and (b)(3) are revised to read as follows:

§ 35.13 License amendments.

(b) * * *

(1) For an authorized user, an individual who meets the requirements in §§ 35.190(a); 35.290(a); 35.390(a) and 35.390(c); 35.392(a); 35.394(a); 35.490(a) and 35.490(c); 35.590(a); 35.690(a), 35.690(c) and 35.690(d); 35.910(a); 35.920(a); 35.930(a); 35.932; 35.934; 35.940(a); 35.950(a); or 35.960(a) and 35.59;

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in §§ 35.59 and—

(i) 35.55(a) and 35.55(c) or

(ii) 35.980(a);

(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.59 and—

(i) 35.51(a), 35.51(c) and 35.51(d) or

(ii) 35.961(a) or (b);

* * * * *

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

§ 35.14 Notifications.

(a) A licensee shall provide the Commission a copy of the board certification and the written certification(s) signed by a preceptor, the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, or the permit issued by a Commission master material license broad scope permittee for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under § 35.13 (b)(1) through (b)(4).

* * * * *

6. In § 35.50, paragraphs (a) and (c) are revised, paragraph (b)(2) is removed and reserved, and paragraphs (d) and (e) are added to read as follows:

§ 35.50 Training for Radiation Safety Officer.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

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

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

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

(b) * * *

(2) [Reserved]

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

(d)(1) Is an authorized user, authorized medical physicist, or

authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; or,

(2)(i) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.51(a) and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and

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

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

7. In § 35.51, paragraphs (a) and (b)(1) are revised, paragraph (b)(2) is removed and reserved, and paragraphs (c) and (d) are added to read as follows:

§ 35.51 Training for an authorized medical physicist.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

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

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

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

(ii) In clinical radiation facilities providing high energy, external beam therapy and brachytherapy services under the direction of physicians who meet the requirements for authorized users in §§ 35.490 or 35.690;

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

(b)(1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high energy, external beam therapy and brachytherapy services and must include:

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

(iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(2) [Reserved]

(c) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (a) or (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51, or, before October 24, 2004, § 35.961, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

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

8. In § 35.55, paragraph (a) is revised, paragraph (b)(2) is removed and reserved, and paragraph (c) is added to read as follows:

§ 35.55 Training for an authorized nuclear pharmacist.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

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

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

(3) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience;

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

(b) * * *

(2) [Reserved]

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

§ 35.57 [Amended]

9. In § 35.57, replace both references to ''October 24, 2002'' with ''[insert effective date of final rule]''.

10. In § 35.190, paragraphs (a) and (c)(1)(ii)(B) are revised to read as follows:

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

* * * * *

(a) Meets the requirements in paragraph (c)(2) of this section and is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Meet the requirements in paragraph (c)(1) of this section;

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

* * * * *

(c) * * *

(1) * * *

(ii) * * *

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

* * * * *

11. In § 35.290, paragraphs (a) and (c)(1)(ii)(B) are revised to read as follows:

§ 35.290 Training for imaging and localization studies.

* * * * *

(a) Meets the requirements in paragraph (c)(2) of this section and is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Meet the requirements in paragraph (c)(1) of this section;

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

* * * * *

(c) * * *

(1) * * *

(ii) * * *

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

* * * * *

12. In § 35.390, paragraph (a), paragraphs (b)(1)(ii)(B), and (b)(1)(ii)(G)(*3*) and (*4*) are revised, paragraph (b)(2) is removed and reserved, and paragraph (c) is added to read as follows:

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

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in paragraph (b)(1) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;

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

(b) * * *

(1) * * *

(ii) * * *

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

* * * * *

(G) * * *

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

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

* * * * *

(2) [Reserved]

(c) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (a) or (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or, before October 24, 2004, § 35.390, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), or, before October 24, 2004, § 35.930(b), must have experience in administering dosages in the same dosage category or categories (*i.e.*, § 35.390(b)(1)(ii)(G)(*1*), (*2*), (*3*), or (*4*)) as the individual requesting authorized user status.

* * * * *

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

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

* * * * *

(a) Meets the requirements in paragraph (c)(3) of this section and is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section and whose certification has been recognized by the Commission or an Agreement State.(Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) or

* * * * *

(c) * * *

(2) * * *

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

* * * * *

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

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

* * * * *

(a) Meets the requirements in paragraph (c)(3) of this section and is

certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section and whose certification has been recognized by the Commission or an Agreement State. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.); or

* * * * *

(c) * * *

(2) * * *

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

* * * * *

15. In § 35.490, paragraphs (a) and (b)(2) are revised, paragraph (b)(3) is removed, and paragraph (c) is added to read as follows:

§ 35.490 Training for use of manual brachytherapy sources.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

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

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

(b) * * *

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490, or, before October 24, 2004, § 35.940, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(c) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490, or, before October 24, 2004, § 35.940, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) or (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.

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

§ 35.590 Training for use of sealed sources for diagnosis.

* * * * *

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

(b) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include —

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology; and

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

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

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

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

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

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

(b) * * *

(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in § 35.690, or, before October 24, 2004, § 35.960, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(c) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (a) or (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690, or, before October 24, 2004, § 35.960, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(d) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Dated at Rockville, Maryland, this 2nd day of December, 2003.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 03–30358 Filed 12–8–03; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM270; Notice No. 25–03–08–SC]

Special Conditions: Boeing Model 747–100/200B/200F/200C/SR/SP/100B SUD/400/400D/400F Airplanes; Flammability Reduction System (Fuel Tank Inerting)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This notice proposes special conditions for the Boeing Model 747–100/200B/200F/200C/SR/SP/100B SUD/400/400D/400F series airplanes. These airplanes, as modified by Boeing Commercial Airplanes, will incorporate a new flammability reduction system that uses a nitrogen generation system to reduce the oxygen content in the center wing fuel tank so that exposure to a combustible mixture of fuel and air is substantially minimized. This system is intended to reduce the average flammability exposure of the fleet of airplanes with the system installed to a level equivalent to 3 percent of the airplane operating time. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for the design and installation of this system. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to ensure an acceptable level of safety for the installation of the system and to define performance objectives that the system must achieve to be considered an acceptable means for minimizing the development of flammable vapors in the fuel tank installation.

DATES: Comments must be received on or before January 23, 2004.

ADDRESSES: Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration, Transport Airplane Directorate, Attn: Rules Docket (ANM–113), Docket No. NM270, 1601 Lind Avenue SW., Renton, Washington, 98055–4056; or delivered in duplicate to the Transport Airplane Directorate at the above address. Comments must be marked: Docket No. NM270. Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Mike Dostert, Propulsion and Mechanical Systems Branch, FAA, ANM–112, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue, SW., Renton, Washington, 98055–4056; telephone (425) 227–2132, facsimile (425) 227–1320, e-mail *mike.dostert@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The most helpful comments reference a specific portion of the proposed special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

All comments received will be filed in the docket, as well as a report summarizing each substantive public contact with FAA personnel concerning these proposed special conditions. The docket is available for public inspection before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this preamble between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these proposed special conditions based on the comments we receive.

If you want the FAA to acknowledge receipt of your comments on these proposed special conditions, include with your comments a pre-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it back to you.

Background

Boeing Commercial Airplanes intends to modify Model 747 series airplanes to incorporate a new flammability reduction system that will inert the center fuel tanks with nitrogen-enriched air. Though the provisions of § 25.981, as amended by Amendment 25–102, will apply to this design change, these special conditions are being proposed to address novel design features.

Regulations used as the standard for certification of transport category airplanes prior to Amendment 25–102, effective June 6, 2001, were intended to prevent fuel tank explosions by eliminating possible ignition sources from inside the airplane fuel tanks. Service experience of airplanes certificated to the earlier standards shows that ignition source prevention alone has not been totally effective at preventing accidents. Commercial transport airplane fuel tank safety requirements have remained relatively unchanged throughout the evolution of piston-powered aircraft and later into the jet age. The fundamental premise for precluding fuel tank explosions has involved establishing that the design does not result in a condition that would cause an ignition source within the fuel tank ullage (tank vapor space). A basic assumption in this approach has been that the fuel tank could contain flammable vapors under a wide range of airplane operating conditions even though there were periods of time in which the vapor space would not support combustion.

Fuel Properties

The flammability temperature range of jet engine fuel vapors varies with the type of jet fuel, the ambient pressure in the tank, and the amount of dissolved oxygen that may be present in the tank due to vibration and sloshing of the fuel that occurs within the tank.

At sea level pressures and with no sloshing or vibration present, Jet A fuel, the most common commercial jet fuel in the United States, and Jet A1 used in most portions of the world, have flammability characteristics that tend to make the fuel vapor-air mixture too ''lean'' to ignite at temperatures below approximately 100°F, and too ''rich'' to ignite at temperatures above 175°F. This range of flammability (100°F to 175°F) is reduced to cooler temperatures as the airplane gains altitude due to the corresponding reduction of pressure. For example, at an altitude of 30,000 feet the flammability temperature range is approximately 60°F to 120°F.

The flammability range of Jet B (JP–4), another fuel approved for use on most commercial transport airplanes but not used as a primary fuel, is approximately 15°F to 75°F at sea level, and −20°F to 35°F at 30,000 feet. Because Jet B fuel flammable temperature ranges as a function of pressure altitude are more within normal temperatures at altitudes, airplane fuel tanks are flammable for a much larger portion of the flight.

Most commercial transports are approved for operation at altitudes in the range of 30,000 to 45,000 feet. The FAA has always assumed that airplanes