[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN: 3150-AH19

Medical Use of Byproduct Material - Recognition of Specialty Boards

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

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

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

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

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

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

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

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

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

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

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

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

SUPPLEMENTARY INFORMATION:

Background

During development of the Part 35 proposed and final rules (August 13, 1998 (63 FR 43516); and April 24, 2002 (67 FR 20249), respectively), there was a general belief that the boards recognized by NRC would meet, or could make adjustments to meet, the new requirements, established by that rulemaking, governing recognition of specialty boards by the NRC and that these boards would continue to be recognized by NRC. However, when applications for recognition were received, the NRC staff determined that, except for one board, the boards did not meet all the requirements specified in the final rule. Specifically, the boards' certification programs failed to meet the requirements in the final rule regarding preceptor certification and work experience. The only board that currently meets the revised requirements is the Certification Board of Nuclear Cardiology because it developed its certification program based on the final rule. The NRC staff held several discussions with the boards to determine whether the boards would modify their certifying process to meet all the requirements specified in the rule.

The current regulations in 10 CFR Part 35 offer three pathways for individuals to satisfy training and experience requirements to be approved as a radiation safety officer (RSO), authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), or authorized user (AU). These pathways are: (1) approval of individual who is certified by a specialty board whose certification has been recognized by the NRC or an Agreement State as meeting the NRC's requirements for training and experience (a "recognized board"); (2) approval based on an evaluation of an individual's training and experience; or (3) identification of an individual's approval on an existing NRC or Agreement State license. For the sake of this discussion, pathway (1) will be referred to as the certification pathway, and pathway (2) as the alternate pathway. For example, in § 35.50, the proposed criteria for meeting training and experience requirements for the certification pathway (1) appear in §35.50(a); those for the alternate pathway (2) appear in §35.50(b); and those for pathway (3) appear in §35.50(c).

On February 19, 2002, in a briefing of the Commission, the Advisory Committee on Medical Uses of Isotopes (ACMUI) expressed concern that if the draft final rule became effective as drafted, there could be potential shortage of individuals qualified to serve as RSOs, AMPs, ANPs and AUs. The ACMUI indicated that, without changes in the draft final rule, the boards would no longer be qualified for recognition by NRC and, therefore, a board's future diplomates could no longer be approved as RSOs, AMPs, ANPs or AUs.

The ACMUI also expressed the concern that the boards might be "marginalized." Specifically, under the draft final rule, to gain approval via the certification pathway, a candidate for certification would have been required to meet all of the requirements in the alternate pathway, thereby imposing more requirements on candidates using the certification pathway for approval. The extra requirements of concern to ACMUI include a specification for length-of-training as well as obtaining a written certification signed by a preceptor. Taken together with other requirements of boards, such as requiring candidates for certification to take written

and/or oral examination, the concern was that candidates seeking approval might bypass the board certification pathway and select the alternate pathway.

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

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

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

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

In an SRM dated February 12, 2003, the Commission approved Option 3, directing the NRC staff to prepare a proposed rule based on the ACMUI's recommendations with certain exceptions. The Commission directed that a list of recognized boards be posted on the NRC's web site, that the preceptor statement remain as written in the current regulations (published April 24, 2002), and that the staff should clarify that the preceptor language does not require an attestation of general clinical competency, but does require sufficient attestation to demonstrate that the candidate has the knowledge to fulfill the duties of the position for which certification is sought. This form of attestation should be preserved both for the certification pathway and the alternate pathway.

The ACMUI briefed the Commission on May 28, 2003, and conveyed their views regarding the Commission's direction to NRC staff, relating to preceptor statements, in SRM-02-0194 (February 12, 2003). The Commission subsequently issued an SRM on June 20, 2003

(M030528B). This SRM directed that the staff continue its development of a proposed rule to modify the training and experience requirements in 10 CFR 35, with appropriate interactions with the ACMUI, so that the revised rule can be in place as promptly as possible. The NRC staff met with the ACMUI via tele-conference on July 17, 2003, to further discuss the ACMUI's comments on the proposed rule.

Discussion

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

Certification Pathway.

For the certification pathway, the current regulations incorporated the more prescriptive requirements for the alternate pathway. The proposed rule would establish separate criteria that a board must meet to be recognized by the NRC or an Agreement State. For the RSO, AMP, and ANP, the proposed criteria include a degree from an accredited college or university, professional experience, passing an examination administered by the board, obtaining a written preceptor statement, and in some cases additional training related to the type of use for which an individual would be responsible. The requirement for passing an examination reflects the

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

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

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

Alternate Pathway.

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

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

Training Specific to Type of Use.

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

Other Changes.

In the current rule, § 35.390(b)(1) specifies that work experience for uses of byproduct material in unsealed form for which a written directive is required must include administering dosages of radioactive drugs involving a minimum of three cases in each of the categories for which the individual is requesting authorized user status. Section 35.390(b)(1)(ii)(G)(3) and (4) refer to parenteral administration of certain radionuclides. The proposed rule would clarify that this training must be with quantities of radionuclides for which a written directive is required.

The NRC supports these changes because, without them, an individual might cite experience with low-level dosages to satisfy requirements for work experience; the changes place emphasis on the need for AUs to have work experience with higher level dosages, for which a written directive is required.

The ACMUI recommended that the requirements for work experience for authorized users in §§ 35.190, 35.290, and 35.390 be changed to require experience with performing quality control check of instruments rather than with calibrating instruments. The proposed rule would effect these recommendations with changes to §§ 35.190(c)(1)(ii)(B), 35.290(c)(1)(ii)(B), 35.390(b)(1)(ii)(B), 35.392(c)(2)(ii), and 35.394(c)(2)(ii). The NRC agrees with this recommendation because ensuring proper function of these instruments involves more than periodic calibration (e.g., checks of functionality, constancy); further, calibration is part of quality control procedures.

Training requirements for authorizations as a medical physicist would be changed in § 35.51(b)(1) to remove credit for a degree in biophysics, radiological physics, and health physics, and add the more general, other physical sciences, as well as engineering and applied mathematics. The requirement for 1 year of full-time training in therapeutic radiological physics would be changed to a more general requirement for 1 year of full-time training in medical physics. Similarly, the requirement for training in a clinical radiation oncology facility would be changed to a requirement for training in "clinical radiation facilities." Pluralizing "facility" makes it possible for candidates to receive training in more than one institution. In § 35.690.(b)(2), the requirement for candidates to be approved as AUs would be changed to broaden the requirement requiring that supervised clinical experience be received in "radiation therapy" rather than in "radiation oncology." These changes are needed to allow for the therapeutic use of byproduct material in applications other than cancer therapy and allowing for T&E to be obtained in more than one facility.

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

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

Preceptor Certification.

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

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

The Commission considered the ACMUI recommendations and determined that the preceptor statement should remain as written in the current rule (published on April 24, 2002). However, the Commission has emphasized that the preceptor language does not require an attestation of general clinical competency, but requires sufficient attestation to demonstrate that the candidate has the knowledge to fulfill the duties of the position for which certification is sought.

Listing of Recognized Boards.

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

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

procedures for listing and de-listing of specialty boards on its web site before the effective date of the final rule, if adopted.

Stakeholder Interactions.

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

A draft of this Federal Register Notice was sent to the Agreement States and the ACMUI for 30-day review and comment. A tele-conference between NRC staff and ACMUI was held on July 17, 2003; approximately 12 Agreement State representatives participated in this conference, notice of which appeared in the Federal Register on July 14, 2003 (68 FR 41665). Comments of the ACMUI, Agreement States, board members, and members of the public provided useful information to the NRC in preparing the proposed rule. A person from the State of Alabama represented the Organization of Agreement States and participated as a member of the working group with the NRC staff in the development of this proposed rule.

Recommendations of the ACMUI.

At the teleconference held on July 17, 2003, the full ACMUI discussed the draft proposed rule. During the teleconference, the ACMUI approved the NRC staff recommendation to broaden the requirement that supervised clinical experience be received in a "radiation

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

Timing of Agreement State Implementation.

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

Section by Section Analysis

Section 35.50 - Training for Radiation Safety Officer.

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

Section 35.51 - Training for an authorized medical physicist.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would be amended to provide separate requirements for a specialty board's certification process. This process would include a requirement to pass an examination, administered by diplomates of the specialty board, which would evaluate knowledge and competency areas that are important to functioning as a medical physicist. A new paragraph (c) would be added to require training related to the type of use for which authorization is sought that includes "hands on" device operation, safety procedures, clinical use, and operation of a treatment planning system. Paragraph (c) would apply to all pathways. In addition, for the alternate pathway (paragraph (b)(1)), the acceptable areas of concentration for degrees would be expanded, and a requirement that the degree be from an accredited college or university would be added. Paragraph (b)(1) would also be amended to list the specific areas for which the individual needs to have training and work experience, instead of referring to other sections of Part 35. Requirements that training be received in an oncology facility would be generalized by removing the word oncology and "facility" would be pluralized to allow for training to be gained in more than one facility.

Section 35.55 - Training for an authorized nuclear pharmacist.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would be amended to provide separate requirements for a specialty board's certification process. This certification process

would include a requirement to pass an examination, administered by diplomates of the specialty board, which would evaluate knowledge and competency areas that are important to functioning as a nuclear pharmacist.

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

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

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

Paragraph (a) would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under § 35.100. A requirement would be added that candidates must pass an examination administered by diplomates of the specialty board. Additionally, paragraph (c)(1)(ii)(B) would be amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments.

Section 35.290 - Training for imaging and localization studies.

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

Additionally, paragraph (c)(1)(ii)(B) would be amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments.

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

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

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

Paragraph (a) would be amended to include a statement that the recognized boards would be posted on the NRC's web page. Paragraph (c)(2)(ii) would be amended to modify the requirement that work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments.

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

Paragraph (a) would be amended to include a statement that the recognized boards will be posted on the NRC's web page. Paragraph (c)(2)(ii) would be amended to modify the requirement that work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments.

Section 35.490 - Training for use in manual brachytherapy sources.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would provide separate requirements for a specialty board's certification process. Additionally, paragraph (b)(2) would be amended to include the Royal College of Physicians and Surgeons of Canada in the listing of organizations that can provide approval of the formal training program.

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

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

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

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under 35.600. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would be amended to provide separate requirements for a specialty board's certification process. Additionally, for the alternate pathway, paragraph (b)(2) would be amended to include the Royal College of Physicians and Surgeons of Canada in the listing of organizations that can provide approval of the formal training program. The requirement for experience in "radiation oncology" in paragraph (b)(2) would be modified to allow for experience in "radiation therapy." A new paragraph (c) would be added to require training in device operation, safety procedures, and clinical use for the type(s) of use for which approval as an authorized user is sought. Paragraph (c) would apply to all pathways.

Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the Federal Register on September 3, 1997 (62 FR 46517), this proposed rule would be a matter of compatibility between NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. The Compatibility Categories for the sections amended in this proposed rule would be the same as the sections in the current regulations. The revisions to §§35.50, 35.51, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.491, 35.590, and 35.690 are classified as Category B. A Compatibility Category "B" designation

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

Plain Language

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

Voluntary Consensus Standards

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

Finding of No Significant Environmental Impact: Environmental Assessment

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

Introduction.

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

The Proposed Action.

The proposed action under consideration is an amendment to the Commission's regulations governing the medical use of byproduct materials (Part 35). The proposed action would change the requirements for recognition of specialty boards whose certification may be used to demonstrate the adequacy of the training and experience of individuals to serve as authorized users, authorized medical physicists, authorized nuclear pharmacists or radiation safety officers. The proposed action would also amend certain requirements for the training

and experience of individuals who do not choose the board certification pathway.

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

Need for the Proposed Action.

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

Alternatives to the Proposed Action.

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

Environmental Impacts of the Proposed Action.

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

Agencies and Persons Consulted and Sources Used.

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

§§ 470 et seq).

Finding of No Significant Impact.

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

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

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

Paperwork Reduction Act Statement

This proposed rule would amend information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The burden includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The proposed rule would revise the criteria for recognition of specialty board whose certification may be used to demonstrate the adequacy of training and experience of individuals to serve as authorized users, authorized medical physicists, authorized nuclear pharmacists or radiation safety officers. The proposed rule would also revise the requirements for demonstrating the adequacy of training and experience for the alternate pathway. The change in burden for

information collection relates to submission and review of applications of specialty boards for recognition and is estimated to be insignificant. Because the burden for this information collection is insignificant, Office of Management and Budget (OMB) clearance is not required. Existing requirements were approved by the Office of Management and Budget, approval number 3150-0010.

Public Protection Notification

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

Regulatory Analysis

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

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading. The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Public File Area O1F21, Rockville, MD. Single copies of the regulatory analysis are available from Roger W. Broseus, Office of Nuclear Material Safety and Safeguards, telephone (301) 415-7608, e-mail, rwb@nrc.gov.

Regulatory Flexibility Certification

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

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

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

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

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

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

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

Backfit Analysis

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

List of Subjects in 10 CFR Part 35

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

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

PART 35–MEDICAL USE OF BYPRODUCT MATERIAL

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

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

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

§ 35.50 Training for Radiation Safety Officer.

* * * * *

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

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

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

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

(4) Obtain written certification signed by a preceptor radiation safety officer that the individual has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; or

* * * * *

(c) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license, or a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.51(a) and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and

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

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

§ 35.51 Training for an authorized medical physicist.

* * * * *

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

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

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

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

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

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

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

(b)(1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use modalities for which the individual is seeking

authorization. This training and work experience must be conducted in clinical radiation facilities that provide high energy, external beam therapy and brachytherapy services and must include:

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

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

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

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

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

4. In § 35.55, paragraph (a) is revised to read as follows:

§ 35.55 Training for an authorized nuclear pharmacist.

* * * * *

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

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

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

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

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

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

* * * * *

§ 35.57 [Amended]

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

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

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

* * * * *

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

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

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

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

* * * * *

(c) * * *

(1) * * *

(ii) * * *

(B) Performing quality control procedures on instruments used to determine the activity

of dosages and performing checks for proper operation of survey meters;

* * * * *

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

§ 35.290 Training for imaging and localization studies.

* * * * *

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

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

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

(3) Obtain written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, that the individual has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200; or

* * * * *

(c) * * *

(1) * * *

(ii) * * *

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

* * * * *

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

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

* * * * *

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

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

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

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

(b) * * *

(1) * * *

(ii) * * *

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

* * * * *

(G) * * *

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

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

* * * * *

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

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

* * * * *

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

* * * * *

(c) * * *

(2) * * *

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

* * * * *

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

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

* * * * *

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

* * * * *

(c) * * *

(2) * * *

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

* * * * *

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

§ 35.490 Training for use of manual brachytherapy sources.

* * * * *

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

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

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

(3) Obtain written certification, signed by a preceptor authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, that the individual has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400; or

(b) * * *

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

* * * * *

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

§ 35.590 Training for use of sealed sources for diagnosis.

* * * * *

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

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

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology; and

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

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

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

* * * * *

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

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

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

(3) Obtain written certification that the individual has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must

be signed by a preceptor authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status;

(b) * * *

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

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

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

satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

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

For the Nuclear Regulatory Commission.

_____
Annette Vietti-Cook,
Secretary of the Commission.