FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: FINAL RULE: MEDICAL USE OF BYPRODUCT MATERIAL - RECOGNITION OF SPECIALTY BOARDS (RIN 3150-AH19)

PURPOSE:

To request Commission approval for publication, in the *Federal Register*, of a final rule to amend 10 CFR Part 35, "Medical Use of Byproduct Material," to modify training and experience (T&E) requirements for recognition of specialty board certification processes.

SUMMARY:

The final rule amends the regulations governing the medical use of byproduct material, to change requirements for recognition of specialty boards whose certification may be used to demonstrate the adequacy of the training and experience of individuals to serve as authorized users (AUs), authorized medical physicists (AMPs), authorized nuclear pharmacists (ANPs), or radiation safety officers (RSOs). The final rule also revises the requirements for demonstrating the adequacy of training and experience for the alternate pathway, and completes action on a petition for rulemaking filed on behalf of the Organization of Agreement States (OAS), PRM-35-17. A regulatory analysis and environmental assessment have been completed to support this rule.

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BACKGROUND:

The current regulations in Part 35 offer three pathways for individuals to satisfy T&E requirements to be approved as an RSO, AMP, ANP, or AU. These pathways are:
(1) approval of an individual who is certified by a specialty board, whose certification process has been recognized by the U.S. Nuclear Regulatory Commission (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 this discussion, pathway 1 will be referred to as the "certification pathway" and pathway 2 as the "alternate pathway."

During development of proposed and final rules for the current regulations in Part 35 (August 13, 1998 (63 FR 43516) and April 24, 2002 (67 FR 20249), respectively], it was generally believed that the specialty boards, whose certification processes were recognized by the NRC would meet, or could make adjustments to meet, the new requirements, established by that rulemaking, governing NRC recognition of specialty boards, and that they would continue to be recognized by NRC. However, when applications for recognition were received, the NRC staff determined that, except for one board, the boards did not meet all the requirements in the final rule for preceptor certification and work experience. To resolve these concerns, the NRC modified the final rule by reinserting Subpart J of Part 35 (as contained in the proposed Part 35 rule) for a 2-year transition period, during which the NRC could work to resolve the problem. The Advisory Committee on the Medical Uses of Isotopes (ACMUI) and its subcommittee on T&E provided recommendations for the approach to revising requirements for T&E during the development of the rule. Membership on the subcommittee included the Agreement State representative to the ACMUI. Subpart J of Part 35 provides for continuing recognition of the specialty boards, listed therein, during the transition period ending on October 24, 2004, as provided for in the current rule published on April 24, 2002. While this remained unchanged in the proposed rule, as discussed below, the effective date of Subpart J has been extended to October 24, 2005, under a separate rulemaking action (69 FR 55736, September 16, 2004).

In a Staff Requirements Memorandum dated October 9, 2003 (Attachment 1), the Commission approved publication of a proposed rule to amend the requirements for T&E in Part 35, "Medical Use of Byproduct Material" (SECY-03-0145, August 21, 2003). The proposed rule was published in the *Federal Register* on December 9, 2003 (68 FR 68549). The comment period closed on February 23, 2004, and 27 comments were received. Comments received from Agreement States, the public, and the ACMUI are discussed in detail in the *Federal Register* notice (FRN) (Attachment 2). The Agreement States are also represented on the ACMUI.

DISCUSSION:

Summary of Changes to Part 35.

The principal changes in regulations in the final rule relate to revising the criteria that a certification board must meet for its certification process to be recognized by the NRC or an Agreement State. Changes have also been made to requirements for T&E in the alternate pathway. The NRC staff implemented the direction from the Commission, in SECY-03-0145, to make various changes to the proposed rule before publication. In particular, the requirement

for a preceptor statement was “decoupled” from requirements for recognition of specialty board certification processes in the proposed rule, published in the *Federal Register* (68 FR 68549). (This approach was followed in the final rule, as was the requirement for preceptor statements to be provided to the NRC by licensees, for approval of applications for individuals to serve as RSOs, AMPs, ANPs, or AUs.) Other significant changes in the final rule, as compared to the proposed rule, are:

- “Attest” and “attestation” are used in place of “certify” and “certification,” in requirements for preceptor statements.

- Agreement States are allowed up to 3 years to adopt the final rule.

- The requirement, in 10 CFR 35.390(b)(1)(ii)(F), for experience with the elution of generators, testing, processing, and preparation of labeled radioactive drugs, is removed from 10 CFR 35.390. (The requirement in 10 CFR 35.390(b)(1)(ii)(c), for calculating, measuring, and safely preparing patient or human research subject dosages, is retained.)

- The requirements for experience with oral and parenteral administrations of byproduct material for which a written directive (WD) is required, currently in 10 CFR 35.390(b)(1)(ii)(G), are removed from the requirements for recognition of specialty board certification processes. However, the regulations continue to require this experience for individuals to qualify as AUs for uses of byproduct material for which a written directive is required under 10 CFR 35.300.

- A new 10 CFR 35.396, entitled “Training for the parenteral administration of unsealed byproduct material requiring a written directive,” is included in the final rule. This allows individuals who do not meet other requirements in 10 CFR 35.390(b)(1), to serve as AUs for parenteral administration of byproduct material for which a WD is required, if they meet the requirements in 10 CFR 35.396.

- Requirements for individuals to serve as RSOs were changed, in 10 CFR 35.50, to include medical physicists who meet new requirements specified therein.

- A requirement is added, for AUs in §§ 35.190, 35.290, and 35.390, and for ANPs in § 35.55, that training in basic radionuclide handling techniques must include a minimum number of hours of classroom and laboratory (‘didactic’) training, for individuals to be approved as AUs and ANPs under the alternate pathway.

- The final rule grants, in part, PRM-35-17 (Attachment 3) by incorporating requirements for minimum hours of classroom and laboratory (‘didactic’) training for ANPs and AUs under the alternate pathway in §§ 35.55, 35.190, 35.290, and 35.390.

- The final rule provides for implementation of amendments by October 24, 2005.

These and other changes to the rule and associated guidance are discussed in more detail in Attachment 4 and the FRN. The NRC staff believes that the final rule provides requirements

that are less prescriptive than those in the current rule and allows for more flexible approaches by specialty boards in setting up their certification processes and requirements. The changes will also permit more flexibility in training programs that lead to certification, steps that will continue to ensure radiation safety while resulting in a reduction of regulatory burden.

Public Comments on Questions Posed Regarding the Proposed Rule.

The NRC posed the following questions in the *Federal Register* notice for the proposed rule (68 FR 68549): (1) Do the proposed revisions to requirements for T&E experience provide reasonable assurance that RSOs, AMPs, ANPs, and AUs will have adequate training in radiation safety? (2) Should the word "attestation" be used in place of the word "certification," in preceptor statements? (3) 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? Twenty-seven comments were received, in the form of letters and e-mails, from representatives of Agreement States, professional societies and certification boards, members of the medical community who may be affected by the amendments to requirements for T&E, and other members of the public. The ACMUI also provided comments on the proposed rule. Although many commenters offered specific recommendations related to question 1, commenters generally supported the proposed rule, and, in general, most comments reflected that the proposed requirements for T&E would be adequate to protect health and safety. Those commenters who offered opinions on question 2 generally supported using "attestation" in place of "certification" in preceptor statements, and the ACMUI's recommendation to make this change was adopted in the final rule. Several Agreement State commenters responded to question 3, and they generally advocated, as discussed below, that the NRC should allow Agreement States the full 3 years to adopt the final rule.

Consultation Process with the ACMUI.

During the transition period after publication of Part 35 in April 2002, the NRC worked with the ACMUI to develop a proposed rule and this final rule, both through ACMUI briefings of the Commission and through NRC/ACMUI meetings. Representatives of Agreement States participated in meetings related to the rulemaking. Details of interactions with the ACMUI during the development of the proposed rule were discussed in SECY-03-0145. The staff continued consultations with the ACMUI, briefing the ACMUI on progress on the proposed rule on November 12, 2003. To facilitate public understanding and stakeholder review of proposed amendments to 10 CFR Part 35, the NRC staff posted a comparison document, with differences between the current and proposed rule highlighted on the NRC's web site (on the rulemaking forum) on December 19, 2003. The NRC staff briefed the ACMUI about the status of the draft final rule and received comments from the ACMUI during its meeting on March 1-2, 2004. The ACMUI also briefed the Commission on March 2, 2004. The ACMUI conducted a public meeting, via teleconference, on March 22, 2004, during which the proposed rule was discussed and additional comments on the proposed rule were provided to the NRC staff. The NRC staff also distributed draft implementation procedures to the ACMUI, for comment, during its meeting on November 12, 2003; and a draft revised NRC Form 313A was distributed for comment on December 20, 2003. Four ACMUI members, including the Agreement State representative, submitted comments on draft implementation procedures to the NRC staff, on December 15, 2003; the ACMUI did not provide any comments on the revised draft NRC Form 313A.

During the public comment period on the proposed rule, Agreement State commenters proposed that requirements for a minimum number of hours of classroom and laboratory ('didactic') training should be added to §§ 35.55, 35.190, 35.290 and 35.390. The ACMUI's subcommittee on T&E was consulted to discuss resolution of this recommendation.

The NRC staff provided a draft of the final rule to the ACMUI and Agreement States on September 17, 2004, for a 30-day comment period, ending on October 18, 2004. The draft final rule included the addition of a requirement for minimum hours of classroom and laboratory training for the alternative pathway to qualify as an ANP, in § 35.55 and for certain classes of AUs, in §§ 35.190, 35.290 and 35.390. The minimum number of hours proposed for classroom and laboratory training (applicable to the alternate pathway only) were as follows: § 35.55 – 200 hours; § 35.190 – 8 hours; § 35.290 – 80 hours, and § 35.390 – 200 hours.

The ACMUI held a public meeting (conducted as a teleconference), on October 5, 2004, to discuss the resolution of the issue. The NRC staff suggested that Agreement States be included in the Teleconference. Approximately 37 representatives of 22 Agreement States participated in the call. The ACMUI also discussed the draft final rule and made recommendations during its public meeting held on October 13-14, 2004. During the meeting, the ACMUI agreed with the minimum number of hours of classroom and laboratory training specified in the draft final rule for the alternate pathway in §§ 35.55, 35.190, and 35.290 but recommended that the minimum for classroom and laboratory training in § 35.390 be 80 hours instead of 200 hours. The resolution of this issue is discussed below.

Interactions with Agreement States.

The proposed and final rules were developed by a working group (WG) that included a representative (from Alabama) of the Organization of Agreement States (OAS). A representative (from New York) of the Conference of Radiation Control Program Directors (CRCPD) was added to the WG in June 2004. As discussed below, an Agreement State representative of the OAS served on a Steering Group formed in June 2004. The NRC staff provided a draft of the proposed rule to Agreement States, on June 24, 2003, for a 30-day comment period. Six comments were received via letters and e-mails. The WG considered these comments during its revision of the proposed rule. Representatives of Agreement States also provided comments on the proposed rule during the 75-day public comment period. These comments are discussed in the FRN for the final rule.

As noted above, the NRC staff provided a draft of the final rule to Agreement States and ACMUI on September 17, 2004, for a 30-day comment period. Agreement State representatives participated in the ACMUI meeting, conducted as a teleconference on October 5, 2004. The NRC staff also distributed draft procedures for listing of recognized board certifications to Agreement States on November 12, 2003. The NRC staff considered the Agreement State comments as the NRC developed the final procedures.

OAS Petition PRM 35-17.

The OAS filed a Petition for Rulemaking dated September 3, 2004 (PRM-35-17, Attachment 3) requesting that the NRC amend §§ 35.55, 35.190, 35.290 and 35.390 to define and specify the minimum number of classroom and laboratory ('didactic') training hours for AUs and ANPs identified in these sections. Notice of receipt of the petition was published in the *Federal*

Register on October 28, 2004 (69 FR 62831). In the Federal Register notice, the NRC indicated that the issues raised in PRM-35-17 would be addressed in the current rulemaking and that the NRC would not be instituting a separate public comment period for this action.

The petition is granted, in part, by inclusion in the final rule of requirements for minimum numbers of hours of classroom and laboratory training, for the alternate pathway, in §§ 35.55, 35.190, 35.290, and 35.390. If the petitioner's request had been granted in full, the requirement for minimum numbers of hours of classroom and laboratory training would also apply to requirements for recognition of board certifications. The NRC staff believes that this would unnecessarily limit the flexibility of boards to determine their certification requirements and might have an adverse effect on the ability of boards to meet the requirements for recognition. The final rule only incorporates requirements for a minimum number of hours of classroom and laboratory into the alternate pathway. Because the petitioner did not distinguish between the alternate pathway and the board certification pathway in the petition, the petitioner's request is granted, in part, and denied, in part. This completes action on PRM-35-17.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication, in the *Federal Register*, the attached notice of final rulemaking (Attachment 2).

2. To satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b), certify that this rule, if promulgated, will not have significant impact on a substantial number of small entities. This certification is included in the attached *Federal Register* notice.

3. Note that:

   a. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).

   b. A final Regulatory Analysis has been prepared for this rulemaking (Attachment 5).

   c. A final Environmental Assessment has been prepared for this rulemaking; it appears in the attached notice of final rulemaking (Attachment 2).

   d. The staff has determined that this action is not a "major rule," as defined in the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 [5 U.S.C 804(2)] and has confirmed this determination with the OMB. The appropriate Congressional and General Accounting Office contacts will be informed (Attachment 6).

   e. The appropriate Congressional committees will be informed of this action.

f. The NRC staff will write a letter to the petitioner for PRM-35-17 to advise the petitioner regarding the disposition of the petition and provide a copy of the final rule.

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

COORDINATION:

The Office of the General Counsel has no legal objection to the final rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. The NRC announced the availability of an Office of Management and Budget (OMB) supporting statement for a 30-day comment period in the *Federal Register* on December 2, 2003 (68 FR 67488). The OMB approved the proposed rule (OMB No. 3150-0010) and the related information collection (NRC Form 313A, OMB No. 3150-0120) on February 2, 2004. Submission of the final rule for clearance is not required.

Luis A. Reyes
Executive Director
for Operations

Attachments:
1. SRM Dated October 9, 2003
2. *Federal Register* Notice
3. PRM-35-17
4. Additional Background on Final Rule and Associated Guidance
5. Regulatory Analysis
6. SBREFA Forms

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