RULEMAKING ISSUE
AFFIRMATION

January 19, 2005 SECY-05-0020

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. The final rule provides a more flexible and performance-based approach to specifying requirements for training and experience, using a graded approach to ensure that training in radiation protection is consistent with the need for adequate understanding and skills. 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 (e.g., identified on a license or permit) 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 work experience and certification by a preceptor (i.e., an individual who provides, directs, or verifies training and experience) of completion of T&E and of competency to function independently as an RSO, AMP, ANP, or AU. To address the potential that individuals would no longer satisfy requirements for T&E under the certification pathway, 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 ensure that appropriate requirements for T&E apply to recognition of specialty board certification processes. The Advisory Committee on the Medical Uses of Isotopes (ACMUI) and its subcommittee on T&E provided recommendations for an approach to revising requirements for T&E during the development of the rule. Membership on the subcommittee included the Agreement State member of the ACMUI. Subpart J of Part 35 provided for continuing recognition of the specialty boards, listed therein, during the transition period which was to end on October 24, 2004, as provided for in the current rule published on April 24, 2002. In order to ensure an effective transition, 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).

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 an SRM dated October 9, 2003, related to 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 (placing the requirement on the individual to obtain the preceptor statement) in the proposed rule, published in the *Federal Register* (December 9, 2003; 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.) 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 under the alternate pathway.

- 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 are discussed in more detail in the FRN (Attachment 2). 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 (December 9, 2003; 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 on April 24, 2002 (67 FR 20249), the NRC worked with the ACMUI to develop a proposed rule on training and experience, and this final rule, both through ACMUI briefings of the Commission and through NRC/ACMUI meetings. 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 held a publicly noticed 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 (a form used to document training experience and to obtain a preceptor statement) 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 '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 terms "didactic training" and "classroom and laboratory training" were used interchangeably by the Agreement States in their comments and both terms are used in the current regulations in Part 35. The term "classroom and laboratory" will be used hereinafter to refer to this type of training.

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. 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 Agreement States' recommendation to require minimum numbers of hours of classroom and laboratory training. 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 passed a motion recommending that the minimum for classroom and laboratory training in § 35.390 be 80 hours instead of 200 hours.

After consultation with the ACMUI and the Agreement States, as discussed in more detail in the FRN (Attachment 2), the NRC staff determined that the final rule should include requirements for a minimum number of hours of classroom and laboratory training, applicable to the alternate pathway only, that is: § 35.55 – 200 hours; § 35.190 – 8 hours; § 35.290 – 80 hours; and § 35.390 – 200 hours. The NRC staff believes that this represents a graded approach (requiring more hours for more complex types of use), taking into account the risks associated with the activities conducted by nuclear pharmacists approved as ANPs under § 35.55 and AUs approved for medical uses of byproduct material under §§ 35.100, 35.200, and 35.300. This

approach ensures that training will be appropriately rigorous for those types of uses for which potential hazards are greater.

The ACMUI also passed a motion, at its meeting on October 13-14, 2004, recommending that medical physicists, who have been authorized to serve as medical physicists for high dose rate brachytherapy, gamma stereotactic radiosurgery, and teletherapy, be "grandfathered" (approved as an AMP) to serve as AMPs for those uses for which they are now responsible for regardless of whether they are currently listed on Agreement State or NRC licenses. Prior to the implementation of current regulations in Part 35 (published on April 24, 2002; 67 FR 20249), the NRC staff evaluated, on a case-by-case basis, the qualifications of individuals to perform the functions of medical physicists and identified them as AMPs on NRC licenses. These individuals are "grandfathered" under §35.57(a). Hence, the concern of the ACMUI would relate primarily to those medical physicists performing functions for licensees of Agreement States but who are not identified on Agreement State licenses. To "grandfather" (approve as AMPs) these medical physicists in an Agreement State, it is necessary to evaluate the training and experience of these individuals to serve as AMPs to ensure that they have achieved a level of radiation safety knowledge sufficient to function independently as an AMP for each type of medical unit for which the individual would be responsible. The NRC staff does not believe that it is appropriate to "grandfather" medical physicists to allow them to serve as AMPs, absent such an evaluation having been conducted. Regulatory agencies in some Agreement States have not been identifying those individuals who have been authorized to serve as medical physicists for the types of use which are of concern to ACMUI. Those regulatory agencies should identify (approve) medical physicists on licences and amendments for the types of use for which status as an AMP is required. This should include previously authorized medical physicists. These individuals, who have been identified on a license, would also be able to serve as preceptors for individuals to become AMPs.

Interactions with Agreement States.

The proposed and final rules were developed by a working group (WG) that included a representative from Alabama, nominated by the Organization of Agreement States (OAS). A representative from New York, nominated by the Conference of Radiation Control Program Directors (CRCPD) was added to the WG in June 2004. An Agreement State representative from Washington State, nominated by the OAS served on a Steering Group formed in June 2004. 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 comments related to the subject of specifying minimum numbers of hours of classroom and laboratory training and other matters such as the acceptability of the NRC not inspecting specialty boards but, rather, waiting to see if medical events occurred; the qualifications of preceptors, and whether a preceptor's authorization on a license is at risk when he signs a preceptor attestation. Discussion of these comments and NRC responses appear in the FRN (Attachment 2) under the heading, "Summary of Public Comments and Responses to Comments." 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 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. The final rule requires 8, 80 and 200 hours of classroom and laboratory training for 35.190, 35.290, and 35.55 and 35.390, respectively. The petition is denied in so far as the NRC is not requiring a minimum number of hours of classroom and laboratory training for the certification pathway. The NRC staff believes that, to do so, would unnecessarily limit the flexibility of boards to determine their certification requirements. The final rule only incorporates requirements for a minimum number of hours of classroom and laboratory training into the alternate pathway. This completes action on PRM-35-17.

Staff Approach to Determining Requirements for Minimum Hours of Classroom and Laboratory Training.

As explained above, during the ACMUI meeting on October 14, 2004, the ACMUI passed a motion recommending that the requirement for classroom and laboratory training, in § 35.390, be 80 rather than 200 hours. The ACMUI believes that the requirements for training in radiation safety and safe handling for medical uses under §§ 35.200 (no written directive required) and § 35.300 (written directive required), including the use of beta emitters, are similar. The total hours of training (classroom and laboratory, combined with work experience) is the same (700 hours) in §§ 35.290 and 35.390. Therefore, the ACMUI recommended that the number of hours required for classroom and laboratory training be the same as that required for § 35.290, i.e., 80 hours, because the knowledge required for radiation safety is similar for uses under both §§ 35.290 and 35.390. The ACMUI was also concerned that time taken for classroom and laboratory training required under § 35.390(b)(1)(I) would detract from time needed for training in other areas required of clinicians.

After consideration of both the ACMUI's and Agreement States' recommendations, the NRC staff analyzed the issue to determine the appropriate amount of classroom and laboratory training for approval of AUs under § 35.390. The NRC staff determined that 200 hours of classroom and laboratory training is the appropriate requirement for the alternate pathway in § 35.390 because more knowledge is necessary in the topic areas listed in § 35.390(b)(1)(i)(A) through (E), as enumerated below, to ensure the safe use of byproduct material for which a written directive is required.

1. Radiation physics and instrumentation – a wide variety of radionuclides, having a wider range of energies, both for beta and gamma emitters, is used. This affects

understanding of how radiation interacts with matter, which impacts understanding of shielding as well as the effects of radiation, and choice and use of instrumentation to detect and measure radiation and to measure quantities of radionuclides.

2. Radiation protection – more knowledge of principles and practices of radiation protection is needed because of the wider variety of radionuclides and associated types and energies of radiations used under § 35.300. Because greater quantities of byproduct material are commonly used for therapeutic purposes, risks are greater for patients and patient care personnel as well as for the public after the release of patients. Evaluation of these risks and associated protective measures and practices necessitates more knowledge for uses under § 35.300 than for uses under § 35.200. More knowledge of principles and practices in radiation protection is needed because of a wider variety of modes of administration and physical forms of byproduct material, e.g., intravenous, intra-peritoneal, oral and liquids in catheters. Each of these factors necessitates different radiation safety considerations for patients, occupationally exposed personnel and members of the public.

3. Mathematics pertaining to the use and measurement of radioactivity – Mathematics related to dosimetry is more complex for the wide variety of radionuclides, greater quantities, different types of radiation, and the broader purposes of use. Whereas byproduct material is used for diagnostic purposes under § 35.290, uses under § 35.390 are common for various therapeutic purposes.

4. Chemistry of byproduct material for medical use – a wide variety of chemical forms of byproduct material is used under § 35.300. These forms include ionic, bound-to-antibodies, and simpler chemical species, resulting in differences in uptake in the body and various organs and tissues (biodistribution), and elimination. Agents are used both for diagnostic and therapeutic purposes.

5. Radiation biology – more knowledge of radiation biology is needed because byproduct material are administered in greater quantities, both for diagnostic and therapeutic purposes, resulting in the potential for a greater variety of radiation effects and greater potential for harm. Risk assessments sometimes involve consideration of immediate biological effects whereas this is not usually a consideration in diagnostic applications under § 35.200.

In addition to these considerations, the NRC notes that new medical applications of byproduct material are evolving under § 35.300. Examples include more common use of byproduct material for alleviation of bone pain and for treatment of metastatic disease. This results in a need for additional knowledge of a wider variety of applications of physical and chemical forms of byproduct material.

OMB APPROVAL:

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.

RECOMMENDATIONS:

That the Commission:

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

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 4).

   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 5).

   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.

/RA Ellis W. Merschoff Acting For/

Luis A. Reyes
Executive Director
for Operations

Attachments:
1. SRM Dated October 9, 2003
2. *Federal Register* Notice
3. PRM-35-17
4. Regulatory Analysis
5. SBREFA Forms

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