UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

SECRETARY

March 7, 2005

COMMISSION VOTING RECORD

DECISION ITEM: SECY-05-0020

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

The Commission (with all Commissioners agreeing) approved the final rule as noted in an Affirmation Session and recorded in the Staff Requirements Memorandum (SRM) of March 7, 2005.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield
Commissioner Jaczko
Commissioner Lyons
OGC
EDO
PDR

VOTING SUMMARY - SECY-05-0020

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. DIAZ	X				X	2/10/05
COMR. McGAFFIGAN	X				X	2/17/05
COMR. MERRIFIELD	X				X	1/27/05
COMR. JACZKO	X				X	2/14/05
COMR. LYONS	X				X	2/14/05

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the final rule as noted in an Affirmation Session and reflected in the SRM issued on March 7, 2005.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN DIAZ

SUBJECT: **SECY-05-0020 - FINAL RULE: MEDICAL USE OF BYPRODUCT MATERIAL - RECOGNITION OF SPECIALTY BOARDS (RIN 3150-AH19)**

Approved xx w/comments and edits Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached.

SIGNATURE

Feb 10, 05

DATE

Entered on "STARS" Yes ✓ No ___

Chairman Diaz's Comments on FINAL RULE – 10 CFR PART 35 "MEDICAL USE OF BYPRODUCT MATERIAL - RECOGNITION OF SPECIALTY BOARDS" (RIN: 3150-AH19)

I approve publication of the Federal Register Notice on Medical Use of Byproduct Material, subject to inclusion of the attached edits. This rule amends the requirement for demonstrating the adequacy of training and experience for individuals through either the training and experience of an individual as certified by the specialty board's certification process or a process that evaluates an individual's training and experience. The final rule also requires the licensee to submit preceptor attestations to the NRC or Agreement State for either process. I agree with Commissioner Merrifield's statement that some of our stakeholders may not be completely pleased with the final outcome of this rulemaking. However, I believe staff has provided a balanced rule that allows flexibility for certification by the specialty boards and provided a consistent way by which the Agreement States can assess an individual's training and experience. Additionally, the rule maintains public health and safety by requiring classroom and laboratory hours commensurate with the risk associated with a specific activity.

received comments which raised the same issues as those raised by the petitioner. Because of the similarity in issues raised, the NRC has determined to consider the OAS petition as part of this rulemaking.

During resolution of the comments, the NRC staff consulted with the ACMUI and Agreement States on how to ensure adequacy of T&E in radiation safety and consistency of requirements for T&E between Agreement States and between Agreement States and the NRC. Agreement State representatives served as members on an NRC working group to develop this rule. A steering group, formed to provide recommendations to resolve the issue raised by the Agreement States related, during comments on the proposed rule, on requirements for classroom and laboratory training. The working group addressed issues raised in the petition related to specifying hours of classroom and laboratory training in 10 CFR Part 35. The NRC staff consulted with and received comments from the ACMUI via a public teleconference on the issue on October 5, 2004, with participation of Agreement States, and during its meeting on October 13-14, 2004. After consideration of the input from these sources, as well as review and analysis of the issue by the working and steering groups, the NRC has determined to grant the petition in part, and is revising §§ 35.55, 35.190, 35.290, and 35.390, in the final rule, to establish a requirement for minimum number of hours of classroom and laboratory training for the alternate pathway. The petition is denied, in part, 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 such a requirement would unnecessarily limit the flexibility of boards to determine their certification requirements. The rationale for this change to requirements for T&E is explained in the NRC's response to comments on the proposed rule in Section IV, Summary of Public Comments and Responses to Comments,

the candidate has the knowledge to fulfill the duties of the position for which certification is sought.

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

The requirement for licensees to submit a preceptor attestation to the NRC appears in revised § 35.14(a).

Listing of Recognized Board Certifications.

The NRC will list on its web site (http://www.nrc.gov), instead of in its regulations, the names of board certifications for those boards whose certification processes meet the NRC's requirements. 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.

Because of the importance of board certification in establishing the adequacy of T&E for individuals to serve as RSO, AMPs, ANPs, and AUs, a clear regulatory determination must be made that all boards, both new and existing, meet the relevant regulatory criteria. Evaluation of board requirements against revised criteria in the final rule is necessary to make this determination. Boards that are currently listed in Subpart J of Part 35 and other boards are

must be applicable only to those who begin training after the date of implementation of the final rule.

Response: The NRC believes that the revisions to requirements for T&E of AUs do not result in such extensive changes from current requirements that it should create difficulty for individuals to document their T&E. The ACMUI noted in its recommendations to the NRC for the development of the proposed rule (see SECY-02-0194) that it expected that the requirements of all boards for certification, and currently recognized, would satisfy revised requirements. Thus, there should be little change in what an individual would be expected to present to a board to gain certification. Further, the changes to the requirements for the alternate pathway are relatively few. Thus, these changes will not make the task of documenting T&E significantly more difficult. The NRC believes that these requirements are essential to ensuring adequacy of T&E for medical uses of byproduct material for which a WD is required and, therefore, that they should not apply only to individuals who begin training after the final rule is implemented. Further, under the provisions of § 35.57(b), experienced AUs (e.g., individuals identified on a license) are not required to comply with requirements for T&E in Subparts D through H of Part 35. Therefore, the suggestion offered by the commenter was not adopted.

Issue 7: Should the term "laboratory training" be defined?

Comment: One Agreement State Commenter expressed concern that the meaning of the term, "laboratory training," should be more clearly defined. The commenter expressed concern that "laboratory" time could be interpreted as "clinical lab" which would be patient-care oriented rather than radiation-safety oriented.

Response: The NRC believes that defining the terms "classroom" and "laboratory" would not ensure compliance and would only serve to create a more prescriptive rule. However, the

Section 35.10 Implementation

Comment: One commenter stated that the current transition period, which ends on October 24, 2004, must be extended to allow time for boards to prepare applications and for processing of applications by the NRC, including review by the ACMUI.

Response: The NRC agrees that additional time for the changes to T&E should be allowed beyond October 24, 2004. Therefore, by way of a separate rulemaking, the NRC has amended 10 CFR Part 35 to extend the expiration of Subpart J for 1 year beyond the current expiration date to October 24, 2005 (69 FR 55736, September 16, 2004). This will allow time for specialty boards to prepare and submit applications for recognition under the revised regulations.

The final rule also contains amendments to requirements for T&E that relate to the alternate pathway and the submission of preceptor statements for board certified individuals under § 34.14(a). The NRC is providing, in § 35.10, for implementation of these requirements by October 24, 2005, to allow time for licensees and license reviewers to adopt revisions to requirements for T&E.

The NRC also notes that those board(s) whose certifications have been recognized by the NRC will continue to be listed on the NRC's web site until Subpart J expires on October 24, 2005; only those boards whose certifications are recognized under the provisions of this final rule will be listed after October 25, 2005.

Section 35.14 Notifications

Section 35.14(a) is being amended to require the submission of statements, signed by preceptors, in addition to a copy of a board's certification (required under current regulations). This change was made as a conforming change necessitated by amendments to requirements

Response: Section 35.57(b)(1) provides the exception sought by the commenter by not requiring AUs to comply with the training requirements in Subparts D through H and to continue performing those medical uses for which they were authorized before October 24, 2002 (the effective date of the current regulations). Section 35(b)(2) allows AUs, authorized between October 24, 2002 and the effective date of this final rule ([insert date 30 days after publication in the Federal Register]) to continue performing those medical uses for which they were authorized during this period. NRC licenses are being modified accordingly.

Comment: The ACMUI recommended that the NRC provide a clarification that, for the diagnostic use of I-131 as sodium iodide which falls under § 35.392 for diagnostic use only, the training which an individual may cite for uses under § 35.392 may also serve as credit as part of the 700 hours of training for uses under § 35.200.

Response: The NRC requirement for 80 hours of training for uses under § 35.392 may be credited towards the 700 hours of training for uses under § 35.200 under the current regulations in § 35.290 and under the final rule.

Subpart E – Unsealed Byproduct Material - Written Directive Required

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

Comment: A commenter indicated that the NRC is imposing a new requirement in its regulations for 700 hours of training for uses for which a WD is required. The commenter indicated that this is 620 hours more than is required for the use of sodium iodide I-131 in quantities up to 1.2 GBq (33 millicuries) for therapeutic applications, for which 80 hours of training is required under § 35.392. Further, an examination is required for recognition of certifications of specialty boards under § 35.390, but not under § 35.392. The commenter

Comment: One commenter suggested that there should be a grandfathering clause in § 35.392 to allow AUs who were permitted to perform diagnostic total body imaging scans, previously under § 35.200, when the scans were classified as "diagnostic" and "therapeutic" rather than as procedures for which WD is required, to continue to perform these procedures.

Response: Section 35.57(a) provides that experienced AUs, identified on a license or permit, are not required to comply with the training requirements in Subparts D through H to continue performing those medical uses for which they were authorized before October 24, 2002 (the effective date of the current regulations). This provides the "grandfathering" requested by the commenter.

Subpart H of Part 35 – Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

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

Comment: One commenter stated that AUs should be required to be neurosurgeons for use of gamma stereotactic radiosurgery treatments because a neurosurgeon is the only trained physician who has the knowledge unique to understanding the neuroanatomy of the brain. The commenter also suggested other changes to regulations, including a recommendation that the NRC require that WDs for gamma stereotactic radiosurgery be signed by both a treating neurosurgeon and radiation oncologist and that a neurosurgeon should be required to be physically present during treatments involving the gamma unit, with the radiation oncologist also present during the initiation of treatment.

Response: The NRC believes that it would be an unwarranted intrusion into the practice of medicine to specify that only neurosurgeons may serve as AUs for the use of byproduct

medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include–

(ii) * * *

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

* * * * *

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, 35.390, or, before October 24, 2005, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

14. In § 35.200, paragraph (b)(2) is revised to read as follows:

§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

* * * * *

(b) * * *

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920; or

* * * * *

such as the program director. However, this qualified individual need not necessarily be an authorized individual, as required of a preceptor by the final rule.

3. New Types of Use

The T&E requirements in the current 10 CFR Part 35 were expanded to address two new types of use that were not considered in the former rule (i.e., remote afterloader units and gamma stereotactic radiosurgery units, as described in § 35.690). These requirements were geared to address unique health and safety issues specific to these types of use. However, the boards' programs do not specifically include T&E for the new types of use. This raises a concern as to how existing qualified individuals will obtain and demonstrate competence in radiation safety in a new type of use.

ALTERNATIVES

Only two alternatives are considered in this regulatory analysis: (1) No action -- retaining the T&E requirements of the current 10 CFR Part 35; and (2) carrying out a rulemaking to modify T&E requirements to address the concerns noted above.

Option 1 (No Action) assumes that no regulatory action is undertaken, which would leave the requirements of the T&E sections of 10 CFR Part 35 unchanged, and would require the boards to modify their certification processes as necessary to comply with the specified requirements. However, with the exception of one specialty board, the specialty boards have indicated that they will not modify their certification processes and consequently the boards' certification processes will not be recognized by the NRC after the expiration of Subpart J on October 24, ~~2004.~~ 2005

When the NRC enacted the current 10 CFR Part 35, the Commission believed that there would be twenty-three specialty boards whose certification processes could be used by individuals seeking authorization as RSOs, AMPs, ANPs, or AUs in order to demonstrate the adequacy of their T&E. However, after October 24, 2004, twenty-two of those specialty boards will no longer be recognized by the NRC or an Agreement State, which effectively eliminates the board

In § 35.2, the definition of Authorized user (AU) is changed to include individuals who qualify as AUs by meeting requirements in paragraphs (a) and (b) of new § 36.396. The definition of Preceptor is changed from "Preceptor means an individual who provides, or directs the training and experience . . .." to read "Preceptor means an individual who provides, directs, or verifies training and experience . . .." This definition is also changed to include individuals who qualify as AUs by meeting requirements in paragraphs (a) and (b) of new § 36.396.

Cost Impacts:

No cost impacts are expected to be associated with this section.

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

Information collection requirements: OMB approval (§ 35.8).

Existing Regulations

Section 35.8(b) enumerates sections for which information collection requirements, contained in Part 35, have been approved by the Office of Management and Budget.

Final Rule Changes

Physician/management hourly rate	$100
Technical staff amendment preparation time, hours:	4
Technical staff hourly rate:	$30
Total annual cost savings to licensees	$4,000

NRC/Agreement States

Total annual amendments avoided (4 NRC, 14 Agreement States)	18
Reduction to NRC/Agreement States amendment review time, hours:	3
NRC/Agreement States hourly rate:	$77
Total annual cost savings to NRC and Agreement States	$4,000
Total annual cost savings from changes to § 35.55	$8,000

Health and Safety Impacts:

None anticipated.

why is there no analysis for 35.57 15 100

Benefits:

Training and experience commensurate with risk and focused on radiation safety. Board certification will be maintained as a viable pathway to meet T&E requirements under 10 CFR Part 35.

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

Existing Regulations

Section 35.190 specifies the T&E requirements for an AU of a radiopharmaceutical for uptake, dilution, and excretion studies.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

SUBJECT: **SECY-05-0020 - FINAL RULE: MEDICAL USE OF BYPRODUCT MATERIAL - RECOGNITION OF SPECIALTY BOARDS (RIN 3150-AH19)**

Approved X w/comment Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached comments.

Edward McGaffigan Jr.
SIGNATURE

Feb 17, 2005
DATE

Entered on "STARS" Yes X No ___

Commissioner McGaffigan's Comments on SECY-05-0020

I approve the publication of the proposed Federal Register Notice containing the final rule on 10 CFR Part 35 entitled "Medical Use of Byproduct Material - Recognition of Specialty Boards".

I agree with my fellow Commissioners and the Chairman that the staff has done an exceptional job throughout this rulemaking effort. The staff has been faced with many challenges over the last few years and I believe they have successfully addressed diverse public comments and developed a clear, balanced, high-quality rulemaking which is protective of public health and safety. The staff should be complimented for its high caliber work and its dedication to this project.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MERRIFIELD

SUBJECT: **SECY-05-0020 - FINAL RULE: MEDICAL USE OF BYPRODUCT MATERIAL - RECOGNITION OF SPECIALTY BOARDS (RIN 3150-AH19)**

Approved ✓ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached comments.

SIGNATURE

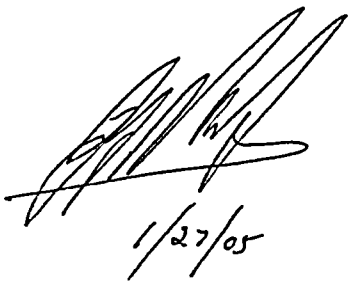
1/27/05

DATE

Entered on "STARS" Yes ✓ No ___

Comments from Commissioner Merrifield on SECY-05-0020:

I approve the final rulemaking package on 10 CFR Part 35 concerning training and experience as recommended by the staff. Reaching this point has been a long road for the staff in dealing with a complex and controversial issue and I compliment the staff for their hard work and diligence. Although there is still considerable effort needed to implement the rule both for NRC licensees and the Agreement States, I want to recognize this significant milestone. In this final rulemaking package, the staff did an excellent job in attempting to address the root concern raised by each stakeholder and was as flexible as reasonable in addressing each issue. While I realize that some of our stakeholders may not be completely pleased with the final outcome of this rulemaking, I believe the staff has done a very good job of ensuring that the Commission was made aware of the variety of viewpoints expressed.



1/27/05

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER JACZKO

SUBJECT: **SECY-05-0020 - FINAL RULE: MEDICAL USE OF BYPRODUCT MATERIAL - RECOGNITION OF SPECIALTY BOARDS (RIN 3150-AH19)**

Approved ✓ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: see attached comments

SIGNATURE

2/14/05

DATE

Entered on "STARS" Yes ___ No ___

Commissioner's Jaczko's Vote on SECY-05-0020
"Final Rule: Medical Use of Byproduct Material - Recognition of Specialty Boards
(RIN 3150-AH19)

I approve the staff recommendation to publish in the *Federal Register* the final rule for 10 CFR Part 35, "Medical Use of Byproduct Material – Recognition of Specialty Boards." From the background material, it is clear that the staff has done thorough work sifting through a complex issue. I applaud their efforts to solicit input from a wide range of interested parties. Since the extensive work to develop this rule occurred prior to my term on the Commission, I defer to the judgment of the staff and the judgment of my fellow Commissioners to approve this rule. Should new issues arise with regard to this rule, I intend to take a fresh look at those issues as they develop.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER LYONS

SUBJECT: **SECY-05-0020 - FINAL RULE: MEDICAL USE OF BYPRODUCT MATERIAL - RECOGNITION OF SPECIALTY BOARDS (RIN 3150-AH19)**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

SIGNATURE

2/14/05

DATE

Entered on "STARS" Yes ___ No ___

Commissioner Lyons' Comments on SECY-05-0020

SECY-05-0020 - FINAL RULE: MEDICAL USE OF BYPRODUCT MATERIAL - RECOGNITION OF SPECIALTY BOARDS (RIN 3150-AH19)

I approve for publication, in the Federal Register, the notice of final rulemaking on the Medical Use of Byproduct Material - Recognition of Specialty Boards. The final rulemaking package reflects considerable staff effort in developing a final rule that has had diverse stakeholder inputs throughout its development. I believe that the final rule will ensure nationwide consistency in determinations of the adequacy of the training and experience of authorized users, authorized medical physicists, authorized nuclear pharmacists, and radiation safety officers. I agree with both the Chairman's and Commissioner Merrifield's comments.

Peter B. Lyons 2/14/05