

**RULEMAKING ISSUE**  
(Affirmation)

July 20, 2004

SECY-04-0127

FOR: The Commissioners

FROM: Luis A. Reyes  
Executive Director for Operations /RA/

SUBJECT: FINAL RULE: MEDICAL USE OF BYPRODUCT MATERIAL -  
MINOR AMENDMENTS: EXTENDING EXPIRATION DATE FOR  
SUBPART J OF PART 35

PURPOSE:

To request Commission approval for publication of a final rule in the *Federal Register* to amend 10 CFR Part 35, "Medical Use of Byproduct Material," to extend the expiration date for Subpart J by 1 year.

BACKGROUND:

On April 24, 2002 (67 FR 20249), the Nuclear Regulatory Commission (NRC) published in the *Federal Register* a final rule amending its regulations regarding the medical use of byproduct material. The final rule addressed, among other things, new training and experience (T&E) requirements and the requirements for recognition of medical and other specialty boards whose certifications may be used to demonstrate the adequacy of the radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, and authorized user. This final rule was effective on October 24, 2002. In addition, NRC retained the existing T&E requirements, designated as Subpart J in Part 35, for a 2-year period. Therefore, Subpart J remains effective until October 24, 2004.

CONTACT: Anthony Tse, NMSS/IMNS  
(301) 415-6233

In the preamble of the 2002 final rule, NRC stated that, during an Advisory Committee on Medical Uses of Isotopes (ACMUI) briefing of the Commission on February 19, 2002, the issue of recognition of medical and other specialty boards was discussed. In that meeting, two committee members expressed concern that some boards did not qualify for recognition and might not be ready to apply for recognition within six months after publication of the final rule. Therefore, implementation of the new Part 35, without Subpart J, could disrupt the current license authorization process for new medical personnel. Therefore, the Commission decided to retain Subpart J for a 2-year period. During this transition period, NRC would continue working with the ACMUI and the medical community to resolve any concerns about the T&E requirements. NRC would consider changes to the T&E requirements, as appropriate.

On December 9, 2003 (68 FR 68549), a proposed rule entitled "Medical Use of Byproduct Material - Recognition of Specialty Boards" was published in the *Federal Register* for a 75-day public comment period. One commenter stated that the current transition period for Subpart J, which ends on October 24, 2004, must be extended to allow time for boards to prepare applications and for NRC to process applications, including ACMUI review. NRC staff agrees with the commenter and believes it is important to provide notice to the medical use licensees and specialty boards that Subpart J will be extended by 1 year.

#### DISCUSSION:

NRC staff plans to publish the attached *Federal Register* notice to extend the expiration date of Subpart J by 1 year. The staff believes that it is prudent to extend the date at this time in order to allow affected stakeholders (i.e., medical and other specialty boards, and medical use licensees) to effectively plan their implementation.

The sections in Part 35 that will be revised by changing the date from October 24, 2004, to October 24, 2005, are § 35.2, paragraph (1) of the definitions of "Authorized medical physicist," "Authorized nuclear pharmacist," "Authorized user," and "Radiation Safety Officer;" §§ 35.10(b) and (c); 35.51(b)(2); 35.100(b)(2); and 35.190(b), (c)(1)(ii) and (c)(2); etc.

Because these amendments constitute minor administrative changes to the regulations, the notice and comment provisions of the Administrative Procedure Act do not apply, pursuant to 5 U.S.C. 553(b)(B). There are no resource implications from this action.

#### RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register*, the attached notice of final rulemaking. This final rule must be effective by Friday, October 22, 2004, 2 days before the expiration date of Subpart J.

2. Note that:

- a. Submission of the final rule to OMB for clearance is not required because this final rule does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995;
- b. A Regulatory Analysis is not necessary for this rulemaking;
- c. An Environmental Assessment is not necessary for this rulemaking;
- 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;
- e. The appropriate Congressional committees will be informed of this action; and
- f. A press release is not necessary for this rulemaking. However, the staff plans to forward a copy of this final rule to medical use licensees and the specialty boards for their information.

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/*

Luis A. Reyes  
Executive Director  
for Operations

Attachment:  
Federal Register Notice

2. Note that:

- a. Submission of the final rule to OMB for clearance is not required because this final rule does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995;
- b. A Regulatory Analysis is not necessary for this rulemaking;
- c. An Environmental Assessment is not necessary for this rulemaking;
- 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;
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Attachment:  
Federal Register Notice

**ML041810048**

\*See Previous Concurrence

<b>OFC</b>	RGB:IMNS		RGB:IMNS		RGB:IMNS		D:IMNS		TechEd		OSTP	
<b>NAME</b>	ATse*		SWastler*		SMoore*		CMiller*		EKraus via email*		PLohaus*	
<b>DATE</b>	06/08/04		06/10/04		06/15/04		06/25/04		06/07/04		06/17/04	

<b>OFC</b>	CIO		ADM		OGC		CFO		D:NMSS		DEDMRS	
<b>NAME</b>	BShelton*		MLesar*		STreby*		JFunches*		JStrosnider		MVirgilio (PLohaus for)	
<b>DATE</b>	06/02/04		06/21/04		06/08/04		06/24/04		07/15/04		07/20/04	

<b>OFC:</b>	EDO			
<b>NAME:</b>	LReyes			
<b>DATE:</b>	07/20/04			