



**American Association of Physicists in Medicine**

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September 13, 2006 (1:19pm)

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

PRM-35-20

Annette L. Vietti-Cook  
Secretary  
Attn: Rulemakings and Adjudications Staff  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-000 1

September 10, 2006

Dear Ms. Vietti-Cook:

On behalf of the American Association of Physicists in Medicine<sup>1</sup> (AAPM) and pursuant to 10 CFR § 2.802, the enclosed petition is submitted to the U.S. Nuclear Regulatory Commission (NRC) to amend 10 CFR § 35.57, *Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist*. The purpose of this petition is to revise the “grandfather” provision of Part 35 to recognize individual diplomates of certifying boards that were previously named in Part 35 prior to October 25, 2005.

Thank you for your consideration. If you have need for any additional information we would be pleased to provide it. If you have additional questions, please contact Lynne Fairobent, AAPM’s Manager of Legislative and Regulatory Affairs at 301-209-3364 or via email at [lynne@aapm.org](mailto:lynne@aapm.org).

Sincerely,

E. Russell Ritenour, Ph.D.  
President

1 Enclosure

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<sup>1</sup> The American Association of Physicists in Medicine’s (AAPM) mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 6,000 medical physicists.



**PETITION FOR RULEMAKING  
TO AMEND**

***10 CFR § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.***

**1. STATEMENT OF PETITIONER'S INTEREST**

The American Association of Physicists in Medicine's (AAPM) mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography, Computed Tomography, Magnetic Resonance, ultrasound, etc.). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery, etc.), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 6,000 medical physicists.

AAPM believes that medical physicists have demonstrated their competence to practice through certification by the American Board of Radiology (ABR) or the American Board of Medical Physics (ABMP). With the change in the NRC process for recognition of certifying boards, AAPM is concerned that only individuals certified after the effective date assigned by the NRC staff, once it recognizes a board's certification process, can use certification to meet the training and experience requirements of the rule. This requires individuals certified prior to the effective date to have to go through the alternate pathway. The medical physics community believes there is no evidence to support a rulemaking assertion that training and education (T&E) requirements for listing as an Authorized Medical Physicist (AMP) or Radiation Safety Officer (RSO) acceptable before October 25, 2005 are no longer acceptable as of October 25, 2005.

**2. BACKGROUND**

A revision of 10 CFR Part 35, *Medical Use of Byproduct Material*, was published on April 24, 2002. (67 FR 20249). This revision contained new T&E requirements for individuals to become authorized as an RSO, AMP, authorized user (AU), and/or authorized nuclear

pharmacist (ANP). These new requirements provided three pathways for an individual to become authorized. These pathways are:

- (1) an individual may be certified by a specialty board whose certification process is recognized by the NRC or an Agreement State as meeting NRC's T&E regulation (a "recognized board");
- (2) approval based on an individual's T&E (alternate pathway); or
- (3) identification of an individual's listing on an existing NRC or Agreement State license (in essence the "grandfathering pathway").

As in the rulemaking, pathway (1) will be referred to as the certification pathway and (2) the alternate pathway.

As indicated by the "Background statement" in 67 *FR* 20249 and 70 *FR* 16335, during a briefing on February 19, 2002 to the Commission, the Advisory Committee on Medical Uses of Isotopes (ACMUI) expressed concern about requirements for T&E in the revised 10 CFR Part 35 approved by the Commission on October 23, 2000 (SRM-SECY-00-0118). The ACMUI was "concerned that if the requirements for recognition of specialty board certifications were to become effective as drafted, there could be potential shortages of individuals qualified to serve as RSOs, AMPs, ANPs, and AUs because they would no longer meet the requirements for T&E under the certification pathway. The ACMUI indicated that, without changes to the requirements for T&E in the final rule approved by the Commission in October 2000, 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." [Emphasis added.]

The ACMUI also expressed the concern that the specialty boards might be "marginalized." "Based on these concerns, the ACMUI urged the Commission to implement measures to address the T&E 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 before publication of the revised Part 35 in April 2002) for a 2-year transition period. [This was subsequently extended for a third year until October 24, 2005 (69 *FR* 55736).] 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, 2002 (67 *FR* 20249) and became effective on October 24, 2002." This rule, as implemented, has in actuality "marginalized" the specialty boards that it intended to recognize.

The Commission directed the NRC staff to develop options for addressing the T&E issue further and to work with the ACMUI and stakeholders (SRM-COMSECY-02-0014). The final T&E rule was published in the Federal Register March 30, 2005 (70 *FR* 16335) and became effective on April 29, 2005. However, in accordance with 69 *FR* 55736, *Medical Use of Byproduct Material Minor Amendments: Extending Expiration Date for Subpart J*, Subpart J was extended to October 24, 2005.

### 3. PROPOSED ACTIONS

First, 10 CFR § 35.57, *Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and*

*authorized nuclear pharmacist*, should be amended to recognize medical physicists certified by either the ABR or the ABMP on or before October 24, 2005, as grandfathered for the modalities that they practiced as of October 24, 2005. This change should be independent of whether or not a medical physicist was named on an NRC or an Agreement State license as of October 24, 2005.

Secondly, 10 CFR § 35.57 should be amended to recognize all diplomates that were certified by the named boards in Subpart J for RSO who have relevant timely work experience even if they have not been formally named as an RSO (or as either an "Assistant or Associate RSO"). These diplomates need to be grandfathered as an RSO by virtue of certification providing the appropriate preceptor statement is submitted.

#### 4. RATIONALE FOR CHANGES

The AAPM, the ABR, and the ABMP believe that it was never the intent of the Commission to deny recognition to any medical physicist currently practicing, or to minimize the importance of certification by a certifying board. This belief is confirmed by our review of the Commission and the ACMUI transcripts. However, since the rule became final, the AAPM, the ABR and the ABMP remain concerned about the NRC's staff's method used to grant recognized status to the process used by certifying boards such as ABR and ABMP.

It has become clear during this review that new concerns regarding diplomates of the certifying boards listed in the original Subpart J have been identified by the medical community. During the review by NRC staff for recognizing the process in place for a certifying board, the NRC staff has assigned "effective dates" for that recognition. As a result, current diplomates of the ABR and the ABMP to serve as AMPs and RSOs must apply via the "alternate pathway" and cannot be listed on a license via the "certification pathway."

The ABR and ABMP believed that the review of their current process was only for diplomates certified after the October 24, 2005, the final date for which Subpart J regulations are effective (see 69 FR 55736 *Medical Use of Byproduct Material Minor Amendments: Extending Expiration Date for Subpart J*). We have affirmed with the boards that they believed that their existing diplomates' certifications (*i.e.*, certificates issued before October 25, 2005) would continue to be recognized by the Commission or an Agreement State. AAPM believes that medical physicists have demonstrated their competence to practice through certification by the ABR or the ABMP. We are concerned that the effective date assigned by the staff once it recognizes a board's process may force individuals certified prior to that date to have to pursue the alternate pathway. AAPM believes that this will place an undue burden on the medical community and potentially result in an insufficient number of AMPs and RSOs.

##### 4.1 Authorized Medical Physicists Amendment

During the revision of 10 CFR Part 35, the NRC added the concept of a medical physicist to be listed on a license. The term "AMP" is a recent construct in both the NRC and Agreement State regulatory structure. Prior to the concept of "AMP" licensing authorities:

1. may have requested a medical physicist to be named on the initial license;
2. may not have required all medical physicists to be listed on a license;
3. may not have required licensees to add additional medical physicists if they joined a

- practice or replaced a “named medical physicist; and
4. Qualified medical Physicists may not have been listed in connection with manual brachytherapy procedures.

This inconsistency in the regulation was the basis for the requirement to list an AMP on licenses, however the requirement also specifies that an individual must have a statement signed by a “preceptor AMP” attesting that the individual is capable of acting independently for the modality specified. Without medical physicists listed on licenses prior to the new regulation, there is limited opportunity for a medical physicist to serve as a preceptor. In order for a medical physicist to be “grandfathered” in accordance with the new regulation, the medical physicist must have been listed on a license as of the effective date of the regulation.

By amending §35.57 in the first case, medical physicists would be recognized by virtue of their certification by the boards listed originally in Subpart J prior to October 24, 2005. This would allow individuals to serve as AMPs or preceptor AMPs without having to be recognized via the alternate pathway. This would not result in grandfathering the boards’ processes but would recognize the diplomates that were certified by the named boards in Subpart J and found competent on or before October 24, 2005, *i.e.*, a “true grandfathering of individuals.” AAPM believes that there have been no health and safety concerns raised by these individuals practicing in medical institutions.

#### 4.2 Radiation Safety Officer Amendment

By regulation, licensees can have only one individual named as a RSO, unlike the position of AU for which there are typically multiple individuals named on a license. This circumstance makes it far more difficult for an AMP or other Board diplomates to have acquired the requisite grandfather status prior to October 24, 2005. Radiation safety and training has been part of the certification exams for physicists for both the ABR (since at least 1979) and the ABMP (since inception of the exam). AAPM believes that the NRC should recognize individuals that were certified by a board that was listed in Subpart J of the old regulations for both §§ 35.50 (RSO) and 35.51 (AMP) prior to October 24, 2005.

#### 5. CONCLUSION

AAPM believes that these proposed solutions should be expedited. Although the certifying bodies are concerned with receiving recognized status, AAPM is concerned about ensuring that the diplomates of the Boards listed in Subpart J are able to continue practicing medical physics and serving as RSOs to assure the continuation of high quality patient care.

AAPM believes that the proposed amendment to 10 CFR § 35.57, *Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist, should be enacted expeditiously to ensure that* diplomates of the Boards listed in Subpart J are able to continue practicing medical physics and serving as RSOs in order to assure the continuation of high quality patient care. Further, AAPM believes that this action eliminates the marginalization of specialty boards.

**From:** "Lynne Fairobent" <lynne@aapm.org>  
**To:** <secy@nrc.gov>  
**Date:** Mon, Sep 11, 2006 8:02 AM  
**Subject:** AAPM Petition for Rulemaking

**\*\* High Priority \*\***

Dear Ms. Vietti-Cook:

Attached is a Petition for Rulemaking from the American Association of Physicists in Medicine related to 10 CFR Part 35.

Please let me know that this has been received.

If you have any questions, please contact me at 301-209-3364.

Thank you.  
Lynne Fairobent

Lynne A. Fairobent  
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**Subject:** AAPM Petition for Rulemaking  
**Creation Date** Mon, Sep 11, 2006 8:05 AM  
**From:** "Lynne Fairobent" <lynne@aapm.org>

**Created By:** lynne@aapm.org

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MESSAGE	493	Monday, September 11, 2006 8:05 AM
TEXT.htm	911	
AMPPetitionfinal9-11-06.pdf	240174	
Mime.822	331876	

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**Expiration Date:** None  
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**ReplyRequested:** No  
**Return Notification:** None

**Concealed Subject:** No  
**Security:** Standard

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