

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[Docket No. PRM-35-20]

E. Russell Ritenour, Ph.D.;
Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; Notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) has received and requests public comment on a petition for rulemaking dated September 10, 2006, filed by E. Russell Ritenour, Ph.D. (petitioner) on behalf of the American Association of Physicists in Medicine (AAPM). The petition has been docketed by the NRC and has been assigned Docket No. PRM-35-20. The petitioner is requesting that the NRC amend the regulations that govern medical use of byproduct material to revise what it calls the “grandfather” provision to recognize individual diplomates of certifying boards that were previously named in these regulations before October 25, 2005.

DATE: Submit comments by (75 days following publication in the *Federal Register*).

Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number (PRM-35-20) in the subject line of your comments. Comments on petitions submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including personal information such as social security numbers and birth dates in your submission.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC

20555. Attention: Rulemaking and Adjudications staff.

E-mail comments to: SECY@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking website at <http://ruleforum.llnl.gov>. Address comments about our rulemaking website to Carol Gallagher, (301) 415-5905; (e-mail cag@nrc.gov). Comments can also be submitted via the Federal eRulemaking Portal <http://www.regulations.gov>.

Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

Publicly available documents related to this petition may be viewed electronically on the public computers located at the NRC Public Document Room (PDR), O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents, including comments, may be viewed and downloaded electronically via the NRC rulemaking website at <http://ruleforum.llnl.gov>.

Publicly available documents created or received at the NRC after November 1, 1999 are also available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this site, the public can gain entry into the NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr@nrc.gov.

A copy of the petition can be found in ADAMS under accession number ML062620129. A paper copy of the petition may be obtained by writing to Michael T. Lesar, Chief, Rulemaking, Directives and Editing Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301-415-7163 or Toll-Free: 1-800-368-5642 or e-mail: MTL@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

The NRC has received a petition for rulemaking dated September 10, 2006, submitted by E. Russell Ritenour, Ph.D. (petitioner) on behalf of the American Association of Physicists in Medicine. The petitioner requests that the NRC amend 10 CFR Part 35, "Medical Use of Byproduct Material." Specifically, the petitioner requests that 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" be revised to recognize medical physicists certified by either the American Board of Radiology (ABR) or the American Board of Medical Physics (ABMP) on or before October 24, 2005, as "grandfathered for the modalities that they practiced as of October 24, 2005."

The NRC has determined that the petition meets the threshold sufficiency requirements for a petition for rulemaking under 10 CFR 2.802. The petition has been docketed as PRM-35-20. The NRC is soliciting public comment on the petition for rulemaking.

Discussion of the Petition

The petitioner notes that a revision of 10 CFR Part 35 was published on April 24, 2002 (67 FR 20249), that contained new T&E requirements for individuals to become authorized as an RSO, AMP, authorized user (AU), and authorized nuclear pharmacist (ANP). The petitioner states that these requirements provide the following three pathways for an individual to become authorized:

- (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 requirements (a recognized board.)

(2) Approval based on an individual's T&E (alternate pathway.)

(3) Identification of an individual's listing on an existing NRC or Agreement State license. The petitioner refers to this option as the "grandfathering" pathway.

The petitioner states that the Advisory Committee on the Medical Uses of Isotopes (ACMUI) expressed the concern during briefings on February 19, 2002, to the Commission on the proposed amendments to Part 35 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 T&E requirements under the certification pathway. The petitioner also states that the ACMUI was concerned that the specialty boards might be "marginalized" and that ACMUI urged the Commission to address T&E issues associated with recognition of specialty boards. The petitioner notes that the NRC modified the regulation by reinserting Subpart J until October 24, 2005.

The petitioner requests that 10 CFR 35.57 be amended to recognize medical physicists certified by either the ABR or ABMP on or before October 24, 2005, "as grandfathered for the modalities that they practiced as of October 24, 2005." The petitioner also states that this amendment "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." The petitioner states that 10 CFR 35.57 should also be amended to recognize all individuals certified by the named boards in Subpart J for RSOs who have relevant work experience even if an individual has not been formally "named" as an RSO and that these individuals "need to be grandfathered as an RSO by virtue of certification providing the appropriate preceptor statement is submitted."

The petitioner states that although the AAPM, ABR, and ABMP recognize that it was

never the NRC's intent to deny recognition to any currently practicing medical physicist or to minimize the importance of a certifying board, these organizations remain concerned about the NRC staff's method used to grant recognized status to the process used by certifying boards. The petitioner is 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. The petitioner indicates that it has affirmed with the ABR and ABMP that they believed that existing diplomates' certifications (i.e., certificates issued before October 25, 2005) would continue to be recognized by the NRC or an Agreement State. The petitioner believes that medical physicists have demonstrated competence to practice through ABR or ABMP certification and remains concerned that the effective date assigned by the NRC staff after it recognizes a board's process may force individuals certified before that date to pursue the alternate pathway. The petitioner believes that the current provision places an undue burden on the medical community and could result in a shortage of AMPs and RSOs.

The petitioner notes that the AMP is a recent addition to licenses granted under 10 CFR Part 35 and Agreement State regulations. The petitioner describes the previous regulations before the concept of the AMP was introduced as "inconsistent." The petitioner believes this inconsistency was the basis for the requirement to list an AMP on licenses. The petitioner also states that this requirement specifies that an individual must have a statement signed by a "preceptor AMP" attesting that the individual is capable of acting independently for the specified modality. The petitioner indicated that without medical physicists listed on licenses prior to the new regulation, there is limited opportunity for a medical physicist to serve as a preceptor. The petitioner believes that for a medical physicist to be "grandfathered" under the new regulation, the individual must have been listed on a license as of the effective date of the regulation. The petitioner has stated that its suggested amendment to § 35.57 would allow individuals to serve as AMPs or preceptor AMPs without having to be recognized via the "alternate pathway."

The petitioner also notes that licensees can specify only one individual as an RSO under the current provisions, unlike the position of AU for which there are typically multiple individuals named on a license. The petitioner believes this makes it more difficult for an AMP or other Board diplomates to have acquired the requisite grandfather status before October 24, 2005. The petitioner has stated that the NRC should recognize individuals who were certified by a board listed in former Subpart J for § 35.50 (RSO) and § 35.51 (AMP) prior to October 24, 2005.

The petitioner concluded that its proposed amendment should be enacted expeditiously to permit individuals certified by the boards listed in Subpart J to continue practicing medical physics and serving as RSOs to assure the continuation of high quality patient care.

Dated at Rockville, Maryland, this 26th day of October 2006.

For the Nuclear Regulatory Commission.

/RA/

Annette L. Vietti-Cook,
Secretary of the Commission.