PRM-35-20
(71FR64168)

American Association of Physicists in Medicine

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Dale E. Klein, Chairman
U.S. Nuclear Regulatory Commission
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September 22, 2008

Dear Chairman Klein:

The American Association of Physicists in Medicine[1] (AAPM) is pleased with the Commission's decision to grant the Association's petition (referred to as the "Ritenour" petition) to amend the regulations "to recognize medical physicists certified by either the American Board of Radiology or the American Board of Medical Physics 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." In addition the Petition requested that "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" [PRM-35-20 "the Ritenour Petition"].

However, we have concerns with the following statement in the Federal Register Notice that announced this decision:

> "[t]he NRC concluded that the issues raised in the petition will be considered in the rulemaking process in the following way. The NRC will attempt to develop a technical basis to support a rulemaking that would address the issues raised in the petition. If a technical basis which supports rulemaking can be developed, the issues will be addressed

[1] 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 6,700 medical physicists.

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> in a future rulemaking. If a technical basis to support a rulemaking cannot be developed, the issues will not be further considered by the NRC." (73 FR 27775).

The Association's concern is that the development of a "technical basis" – which we believe was considered in the NRC Working Group and Petition Review Board deliberation on the petition – will unnecessarily consume significant amounts of time, as well as NRC staff and industry resources, to address a fairly straightforward issue. Furthermore, it is unclear what type of technical basis will be viewed as sufficient, and what methodology would be used to gather such data.

During the July 21, 2008 public conference call of the Advisory Committee on Medical Use of Isotopes (ACMUI), NRC rulemaking staff stated "that if a technical basis is not submitted and is not valid this rulemaking will not occur. It is up to the NRC Medical Staff to prepare the technical basis." The decision to refer this action back to the NRC Medical Staff is troubling to the medical community, as it is this staff that did not understand the significance of the action taken when assigning an effective date to recognizing the certifying boards. It is due to this action that the request for rulemaking was originally tendered. Examples of the negative impact of the staff decision were provided to the Commission as recently as the April 28, 2008 briefing of the ACMUI to the Commission.

The value of the Commission process, which uses a Working Group and Petition Review Board to decide on the validity of a Petition, is that it allows for a broader staff and management review. In the case of the Ritenour Petition, however, it appears that an unusual course of action has been taken, raising the threshold for undertaking a rulemaking. The development of a new technical basis has been tasked to the same staff that has resisted the action requested in the petition.

This would also seem contrary to the Commission's desire that the staff "should work with Committee and the Agreement States to provide recommendations to the Commission on amending NRC's requirements for preceptor attestation for both board certified individuals and amending the attestation requirements for individuals seeking authorization via the alternate pathway, including consideration of additional methods such as the attestation being provided by consensus of an authoritative group. Recommendations should be provided to the Commission in a timely manner to address potential shortages of authorized individuals, particularly in rural areas." May 15, 2008 Staff Requirements Memorandum (SRM) [reference M080429]

During the July 21, 2008 ACMUI conference call, the NRC Medical Staff indicated that they intended to contact the certifying boards (those previously listed in Subpart J to 10 CFR 35 and those currently recognized) to solicit information on the number of individuals certified prior to the Part 35 rulemaking. They also stated that they would ask the boards how many certified individuals are still practicing and who now or in the future may be listed on a license. AAPM contends that anyone who is certified has the potential to be listed on a license. We also maintain that the certifying boards have no knowledge regarding the number of individuals currently listed on a license and certainly not for what modality. Literal application of the staff methodology for gathering data to support a technical basis would result in a misleading conclusion. Rather, an

adequate methodology would be to ask the Boards to provide an estimate of the number of diplomates holding current certifications issued prior to October of 2005 and then have the NRC recognize that each of them in practice may be called upon to serve as an AMP, AU or RSO. All diplomates are at risk for unnecessary impediments to being named on a license now and for the duration of their careers. This impact pattern is now well established and recognized by the professional community, the ACMUI, the Working Group and the Petition Review committee Indeed, this was a central thesis in the PRM, and was affirmed by the Commission in granting the petition. The sole group who has failed to recognize this impact is the NRC Medical Staff.

AAPM remains concerned about the decisions by the Commission to recognize certifying board and their diplomates are adversely impacting patient access to care.

I would be happy to discuss this with you. Please contact me or Lynne Fairobent, AAPM's Manager of Legislative and Regulatory Affairs at 301-209-3364 or via email: lynne@aapm.org.

Sincerely,

Gerald A. White, Jr., M.S., FAAPM

cc: Commissioner Jaczko
Commissioner Lyons
Commissioner Svinicki
R. William Borchardt, EDO
Charles Miller, Director FSME