The AAPM should develop protocols generically, and avoid documents that are too strict and prescriptive, to facilitate their adoption by regulatory agencies like the Nuclear Regulatory Commission and States

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(Received 15 December 1999; accepted for publication 15 December 1999)  

FOR THE PROPOSITION: Cynthia Jones  
Opening Statement  
Since the enactment of the National Technology and Transfer Act of 1995 [Public Law (P.L.) 104-113] on March 7, 1996, all Federal agencies are required to use standards developed by a consensus body. Although one could argue that the AAPM is not listed as one of the “official” standards consensus bodies that are identified on the National Institutes of Standards and Technology website [like the American National Standards Institute (ANSI)], the proto-
Rebuttal

The intent of P.L.104-113 and OMB Circular A-119 is to use already existing standards (or protocols in AAPM’s case) in lieu of an agency drafting new regulations. If NRC incorporates a standard or protocol into a regulation in its entirety, it would not be able change any ‘‘shoulds’’ to ‘‘shall,’’ because that would require a change to the standard itself. I am not proposing, as the opposition states, that the AAPM, or any other standards developing organization, write minimalist standards. Indeed, I am recommending that these bodies more carefully consider what is essential, versus what is purely optional for licensees to do in the course of a particular practice. Perhaps wording such as ‘‘Suggested Best Practices’’ in protocols would clearly delineate those ideas that could improve a practice, but yet are nonessential. Without suggested good practices from societies like AAPM, regulatory agencies would be at a great disadvantage in having to expend resources to develop their own guidance documents, which is exactly not what was the intent of P.L. 104-113. Carefully consider what is required of licensees in any AAPM protocols. Through the use of OMB Circular A-119, you’ll get what you asked for.

AGAINST THE PROPOSITION: Bruce Thomadsen, Ph.D.

Opening Statement

In many AAPM documents we walk a fine line that never quite gets resolved in the organization: Whether recommendations should describe minimum acceptable standards of practice or something better. As the technology and our understanding improve, we, as a community, like to believe that the level of care we can provide our patients also improves. Although the previous minimum standard usually remains safe and as efficacious as before, we like to suggest that our members hold their practice to the improved level. We also like our documents to be comprehensive, covering all possible aspects of a problem.

AAPM protocols for calibration and quality assurance serve two basic functions: (1) to provide guidance for members performing specific functions, and (2) to improve the state of practice. For both of these functions, the protocols often contain recommendations considered absolutely necessary, demarcated by the use of ‘‘shall,’’ and other recommendations that would improve patient care but remain dispensable, indicated by ‘‘shoulds.’’ The ‘‘shoulds’’ help refine a practice and often provide layers of safety or assurance in treatments, at the cost of additional time and resources. Leaving these recommendations optional, the AAPM recognizes that few or no programs can afford the dedication of personnel or funds to perform all suggestions. Nor do all suggestions apply to all situations. Compliance with all recommendations in the reports of Task Groups 40, 53, 56, 59, and 64 alone requires more staffing than reimbursements allow. Yet, the suggested recommendations frequently help practitioners deal with specific situations, and avoiding inclusion would leave members without valuable guidance.

Regulatory bodies often cannot use the word ‘‘should’’ in rules as the AAPM does. In translating recommendations into regulations, some agencies simply change all ‘‘shoulds’’ to ‘‘shall,’’ adding requirements to perform certain actions uselessly in many situations. Adopting a protocol en bloc, such as, ‘‘User shall follow AAPM TG#'’ can be interpreted as requiring all precepts.
To avoid this unpleasant consequence of good intentions, the proposition suggests writing minimalist protocols such that no one could object to performing all parts. Unfortunately, this approach not only eliminates guidance though suggestions, but also loses opportunities to raise the quality of patient care. Such an approach also means that no protocol document would collate all relevant information, leaving members to comb through the literature themselves.

Although possibly uncomfortably increasing the workload for some practicing medical physicists, the inclusion of some or many protocol recommendations into regulations often provides the justification for increasing the staffing levels in some programs.

To serve best the AAPM membership and patients under our care, the Association should continue to draft protocols addressing the state of the art, including necessities and suggested “niceties.” During comment periods in regulation formulation, the Association must lobby for inclusion of the necessary concepts, without adoption of the optional suggestions. To follow the proposition would set all standards to the lowest common levels.

**Rebuttal**

In an era of “right-sizing,” it does make sense not to reinvent anything (or at any other time for that matter). It would serve the society as a whole well for regulatory bodies to make use of AAPM protocols. However, simply copying over the protocols into regulations is a case of good advice making bad laws. One suggestion to avoid mass adoption of AAPM recommendations into regulations might be to keep official protocols very basic, and move all optional recommendations into less official formats. In many cases, though, such a procedure would gut the true substance of the protocol, and certainly make links between the two documents more difficult. Nor would that prevent agencies from incorporating the less official documents. Examples of misdirected good intentions abound (such as Minnesota’s establishing an exposure limit for the general public of 0.054 mR/y), and some state legislator may think that incorporation of all the bells and whistles would benefit their constituency.

Thus, with no guarantee of control over the fate of our documents, we could prepare for the worse, creating only minimalist recommendations that everyone (and their mother or father) could satisfy. This approach would put the AAPM out of the science business, leaving us as a self-serving professional (or unprofessional) organization. Or we could continue to write protocols we consider in the best interest of the patient and society, reflecting the state-of-the-art and improving the state-of-the-practice, and diligently comment during regulation generation. All AAPM documents go through extensive review in the Association, from the task group, through committee and council, and often by the Board and journal reviewers. This process usually leads to high quality, thoughtful recommendations. We should trust ourselves enough to continue this course.