# POINT/COUNTERPOINT

*Suggestions for topics suitable for these Point/Counterpoint debates should be addressed to the Moderator: William R. Hendee, Medical College of Wisconsin, Milwaukee: whendee@post.its.mcw.edu. Persons participating in Point/Counterpoint discussions are selected for their knowledge and communicative skill. Their positions for or against a proposition may or may not reflect their personal opinions or the positions of their employers.*

## 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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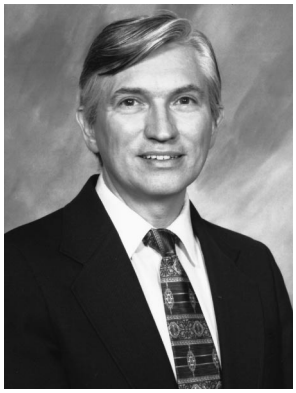
### OVERVIEW

Clinical physicists have the most knowledge about specific calibration and quality control protocols needed to assure the optimized use of ionizing radiation for diagnostic and therapeutic purposes. Many individuals, including some in regulatory agencies, believe that physicists should develop these protocols without concern for extraneous influences such as rules and guidelines from regulatory agencies. However, development of a protocol without concern for regulations creates an enigma for the practicing medical physicist, because following the protocol could result in noncompliance with regulations. This enigma could be resolved if regulatory agencies were willing and able to respond quickly to new protocols, but bureaucracy of the agencies may interfere even if the agencies wished to respond rapidly. Hence, most protocols in medical physics are built to encompass regulations rather than to optimize the procedures they are designed to address. This issue of Point/Counterpoint addresses the intrinsic conflict between existing regulations and protocol development.

Arguing for the Proposition is Cynthia Jones. Cynthia Jones is the Senior Assistant for Materials, Office of Commissioner Dicus, Nuclear Regulatory Commission (NRC). Before joining the Commissioner's staff in July 1999, she was the Senior Level Advisor for Health Physics at the NRC. In that position, she helped develop an NRC Management Directive on the Development and Use of Consensus Standards. Ms. Jones will receive her Ph.D. in nuclear engineering from the University of Maryland in September 2001. Before working at the NRC, she was a physicist at NIST, and a medical and reactor health physicist at UCLA.



Arguing against the Proposition is Bruce Thomadsen, Ph.D. Dr. Thomadsen, a member of the Medical Physics Department of the University of Wisconsin, specializes in radiotherapy physics and radiation safety. He has participated in the development of task group recommendations (compromising as necessary), and with the development of new radiation regulations for the State of Wisconsin. One of the main thrusts of his work has been in quality achievement and error prevention in patient treatments.

### 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-

cols it develops use a consensus process within its professional organization. An interesting aspect to this law is that if a Federal agency uses its own standards (i.e., a regulation developed by an agency for its own use) in a regulation, instead of using an existing consensus standard, it must justify the reason for not adopting the standard and provide a yearly report from the head of that agency to the President's Office of Management and Budget (OMB).

In order to effectively communicate how this law was to be implemented at Federal agencies, OMB issued its revised Circular A-119, ''Federal Participation in the Development and Use of Voluntary Consensus Standards and Conformity Assessment,'' on February 19, 1998. In that circular, OMB also requires that when promulgating a proposed rule, a Federal agency must include a statement that identifies when a voluntary consensus standard is being proposed for use, or when a government unique standard is proposed instead of a voluntary consensus standard. In the latter case, the agency must provide a preliminary explanation of why use of a voluntary consensus standard is inconsistent with applicable law, or is otherwise impractical (Note: OMB defines ''impractical'' as including circumstance in which use of the consensus standard would fail to serve the agency's program needs; would be infeasible, inadequate, inefficient, or inconsistent with the agency's mission; would impose more burdens, or would be less useful than the use of another standard). In addition to this statement, Federal agencies must now also invite public comment as to whether or not the public knows of an existing standard which should be used in lieu of the proposed regulation.

In developing its proposed regulations since the enactment of P.L.104-113, NRC staff now consistently reviews the technical literature for determination of any consensus standards or technical professional societies guidance documents, such as AAPM protocols, that may be used in lieu of the proposed rule or referenced in a proposed regulation or guidance document. Considering the subject at hand, if AAPM were to have developed protocols which could be viewed as suggested recommendations, for example, for calibration and quality control use that were not in conflict with an existing national consensus standard (such as an ANSI), there would be incentive indeed for the NRC to use that instead of development of a new rule, or at a minimum, add that protocol to the list of references which would provide licensees with guidance in this area. In an era of ''right-sizing'' government, it makes good sense to not reinvent the wheel, but rather to use already existing professional societies' protocols for use in new regulations.

### 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 ''shalls,'' 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 ''shalls,'' 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.