

**U.S. Nuclear Regulatory Commission (NRC)
Advisory Committee on the Medical Use of Isotopes (ACMUI)
Subcommittee on ACMUI Bylaws**

Draft Report Submitted On March 7, 2019

Subcommittee Members: Robert Schleipman, Michael Sheetz, Megan Shober,
Laura Weil (Chair)
NRC Staff Resource: Sophie Holiday

Subcommittee Charge:

Review ACMUI Bylaws and recommend updates, with particular focus on the question of whether the ACMUI Chair may serve as a member or chair of any ACMUI subcommittee.

Subcommittee process:

The Subcommittee and its Chair were appointed by the ACMUI Chairman, Dr. Chris Palestro, at the fall 2018 ACMUI meeting.

The Subcommittee members reviewed ACMUI Bylaws to determine whether the existing ACMUI Bylaws addressed the issue of Chair participation in subcommittee proceedings. Suggestions for possible revision regarding that question and any other concerns were made. A draft report was crafted by the Subcommittee Chair and was circulated to all Subcommittee members. The draft report was discussed, amended as necessary, and submitted to the full ACMUI for discussion at the spring 2019 meeting April 3-4, 2019.

Issues considered:

1. Should the ACMUI Chair be allowed to participate on subcommittees? If so, in what capacity should the ACMUI Chair participate? What language, if any, should be added to the Bylaws to clarify this question?
2. What other clarifications or additions to the ACMUI Bylaws, if any, should be considered?

Discussion:

1. ACMUI Chair participation on subcommittees

It has been the practice of the NRC to prohibit the participation of the ACMUI Chair in subcommittee deliberations and recommendations. This was recently brought to the attention of the incoming ACMUI Chairman, Dr. Palestro, who was asked to relinquish his position as Chair of an ongoing subcommittee in anticipation of his role as ACMUI Chairman. Dr. Palestro felt that this issue should be investigated by a subcommittee, and an explicit recommendation be made to the ACMUI, with potential clarification in the ACMUI Bylaws. The current ACMUI Chair and Vice Chair would not vote on the recommendations put forth by this Subcommittee.

The ACMUI Bylaws do not address this point, nor does the ACMUI Charter. The documents of our sister NRC Federal Advisory Committee Act (FACA) Committee, Advisory Committee on Reactor Safeguards (ACRS) are also generally silent on this issue, although the ACRS Chair is the designated Chair of a standing subcommittee. The ACMUI has no standing subcommittees, per its charter. There is no discussion of this issue on the FACA website, nor did consulted FACA staff suggest any required position on the issue. Several other FACA committee bylaws and charters were reviewed by the Subcommittee; none had explicit language regarding the potential for Chair membership and participation in subcommittee work. The understood rationale for the existing informal prohibition of the ACMUI Chair on subcommittees is two-fold: a) the role of Chair is onerous and time-consuming. It would be an imposition to expect the Chair to undertake additional subcommittee responsibilities, and b) the Chair might exert undue influence on subcommittee deliberations. Section 1.3.6 of the ACMUI Bylaws explicitly states, "The Chair may take part in the discussion of any subject before the ACMUI and may vote. The Chair should not use the power of the Chair to bias the discussion. Any dispute over the Chair's level of advocacy shall be resolved by a vote on the Chair's continued participation in the discussion of the subject."

Each member of the ACMUI has a specific area of expertise. In some cases, there is no duplication of expertise among the ACMUI members. The Subcommittee felt that all subcommittees should be able to avail themselves of the relevant expertise of any member of the ACMUI. The potential for benefit of specific expertise on any given subcommittee outweighs the potential for undue influence by the position of Chair. The example given was the recent subcommittee relating to gamma stereotactic radiosurgery (GSR) licensing guidance. Only one member of the ACMUI had specific and significant GSR expertise. Had that one member been the ACMUI Chair, and prohibited from subcommittee participation, the subcommittee would have been deprived of essential information and input in its deliberations. Concern was expressed that ACMUI Chair participation on a subcommittee should not overburden or compromise the ability of the Chair to perform the duties of ACMUI Chair; so it is proposed that the ACMUI Chair should not be asked to serve as any subcommittee chair.

The Subcommittee also discussed whether explicit Bylaws language is required to address this question (or whether a formal position expressed and captured at the ACMUI meeting would be adequate). The membership of the ACMUI turns over completely every eight years or sooner, and NRC staff rotate in and out of the medical team with unpredictable frequency. It is challenging to research areas of tradition and practice such as this. The minutes and transcripts of ACMUI meetings, while available, are not indexed by subject. It was felt that there are potential limits to ACMUI institutional memory, such that inclusion of specific language in the Bylaws would be the most efficient way to address this issue. New language is suggested (in bold italics) to be inserted in the existing Bylaws statement regarding ACMUI Chair discussion, participation, and voting rights. Section 1.3.6):

“The Chair may take part in the discussion of any subject before the ACMUI and may vote. The Chair should not use the power of the Chair to bias the discussion. Any dispute over the Chair’s level of advocacy shall be resolved by a vote on the Chair’s continued participation in the discussion of the subject.” ***In matters where the ACMUI Chair’s unique experience and knowledge would be especially informative, the Chair may serve on relevant subcommittees. In these instances, the ACMUI Chair will not chair the subcommittee.***

2. Additional Bylaw additions

The Subcommittee felt that the existing language in the Bylaws regarding conflict of interest was vague. The bylaws currently state:

4. CONDUCT OF MEMBERS

4.1 If a member believes that he or she may have a conflict of interest with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and the DFO as soon as possible and before the ACMUI discusses it as an agenda item. ACMUI members must recuse themselves from discussion of any agenda item in which they have a conflict of interest.

It is suggested that the ACMUI Bylaws be amended to include additional language to clarify more completely what constitutes a conflict of interest for ACMUI members. The following language is used in the ACRS Bylaws, Section 10.2-2, defining what constitutes a financial conflict of interest and should be considered for amending the ACMUI Bylaws:

Members cannot personally and substantially participate in the review of any particular matter (including general matters such as a rulemaking) that could directly and predictably affect their personal financial interest or the financial interest of:

- Their spouse or minor child
- Their general partner or organization in which they serve as an officer, director, trustee, general partner, or employee
- An organization with which they are negotiating or have an arrangement for prospective employment

However, the Subcommittee welcomes staff input on other language that will provide adequate clarification.

Summary of recommendations:

- The Subcommittee recommends that the ACMUI Chair be permitted to serve as subcommittee member (not chair) when his/her specific expertise is necessary. A specific statement to that effect should be included in the ACMUI Bylaws.

- The Subcommittee recommends that more explicit language be included in the ACMUI Bylaws defining conflict of interest with respect to participation of individual ACMUI members in discussion of matters that come before the Committee.

Respectfully submitted.

The ACMUI Bylaws Subcommittee