

1 *Report of*
2 *Proposed Amendments to ACMUI Bylaws*
3 *Advisory Committee on Medical Uses of Isotopes (ACMUI)*
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6 **Subcommittee Members:**
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8 **Orhan Suleiman, Laura Weil, and Pat Zanzonico (Chair)**
9

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19 **Introduction**

20 The Sub-Committee on Proposed Amendments to Bylaws of the Advisory Committee on
21 Medical Uses of Isotopes (ACMUI) to the Nuclear Regulatory Commission (NRC) was charged
22 with the following tasks:

- 23 1. Discuss, address, review and identify any additional amendments to the amended ACMUI
24 Bylaws originally proposed in September 2013;
- 25 2. Discuss, address, and make a recommendation for the ACMUI reporting structure (MSSA
26 director versus the Commission);
- 27 3. Discuss, address, and make a recommendation for the consideration of budgeting for an
28 additional face-to-face meeting at Headquarters; and
- 29 4. Consider the feasibility of conducting meetings using the Go-To-Meeting™ or Go-To-
30 Webinar function™.

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32 These tasks are addressed in numerical order below.
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35 **1. Discuss, address, review and identify any additional amendments to the ACMUI Bylaws**

36 The Bylaws describe the procedures to be used by the ACMUI in carrying out its duties and
37 the responsibilities of the Committee members. These duties are as follows: "...to provide
38 objective and independent advice to the NRC staff in the Division of Materials Safety and
39 State Agreements, Office of Federal and State Materials and Environmental Management
40 Programs (FSME), with respect to the development of standards and criteria for regulating
41 and licensing medical uses of byproduct material." The proposed Bylaws largely duplicate
42 the previous version of the ACMUI Bylaws, dated October 24, 2006.
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45 **General Comments**

46 **a. NRC Legal Counsel review**

47 Some issues that are considered in the Bylaws and, more generally, that may come before
48 the ACMUI have legal implications and may, as recommended by NRC staff, require input
49 from Legal Counsel for their ultimate resolution. It would helpful to include an explicit
50 statement to this effect somewhere in the Bylaws, perhaps in the Preamble.
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52 **b. § 1.1.5: Webcasting of public portions of ACMUI meetings**

53 Section § 1.1.5 states that. “Portions of ACMUI meetings that are open to the public will be
54 webcast...” Should this be generalized to include all electronic-dissemination modalities by,
55 for example, changing the term, “webcast,” to, “broadcast or otherwise electronically
56 disseminated (eg webcast)”? More importantly, the use of the word, “will,” implies that an
57 ACMUI meeting could not proceed even if webcasting or other electronic dissemination
58 were not possible. A provision should be considered to allow an ACMUI meeting to proceed
59 even if webcasting or other electronic dissemination were not technically do-able. Perhaps
60 § 1.1.5 should be revised as follows, “Portions of ACMUI meetings that are open to the
61 public will be webcast whenever possible, with closed captioning in accordance with the
62 Americans with Disabilities Act.
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64 **c. § 3.1: Term limits of ACMUI members**

65 The immediate past ACMUI Chair, Dr. Leon Malmud, served three terms, so a mechanism
66 for granting an exemption from the two-term limit is in place. The Sub-Committee therefore
67 recommends including a statement in Section § 3.1 noting that exemptions to the two-term
68 limit may be granted.
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71 **Specific Comments**

72 **Pg 2, § 1.1.1** There is some concern that, as written, this provision
73 potentially allows arbitrary cancellation of the annual meeting
74 between the Commission and the ACMUI. Language
75 specifying the circumstances under which these meetings can
76 be cancelled should be included, therefore.
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78 **Pg 2, § 1.1.1 Line 5** The phrase, “...of the ACMUI...,” should be inserted between
79 the words, “Chair” and “declines.”
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81 **Pg 2, § 1.1.3** Are all ACMUI meetings and all portions of meetings
82 transcribed/recorded or only those portions of meetings open
83 to the public? This point should be addressed explicitly in the
84 Bylaws.
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86 **Pg 2, § 1.1.6 Line 1** We suggest changing the phrase, “All meeting handouts will
87 be electronically transmitted...,” to, “All available meeting
88 handouts should be electronically transmitted...”
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90 This suggested change would potentially avoid cancellation of
91 a scheduled ACMUI meeting in the event that not all handouts
92 were available for distribution two weeks prior to the meeting.
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94 **Pg 2, § 1.1.7 Line 1** For the same reason for the suggested revisions to § 1.1.6, we
95 suggest the word, “will,” be changed to, “should.”
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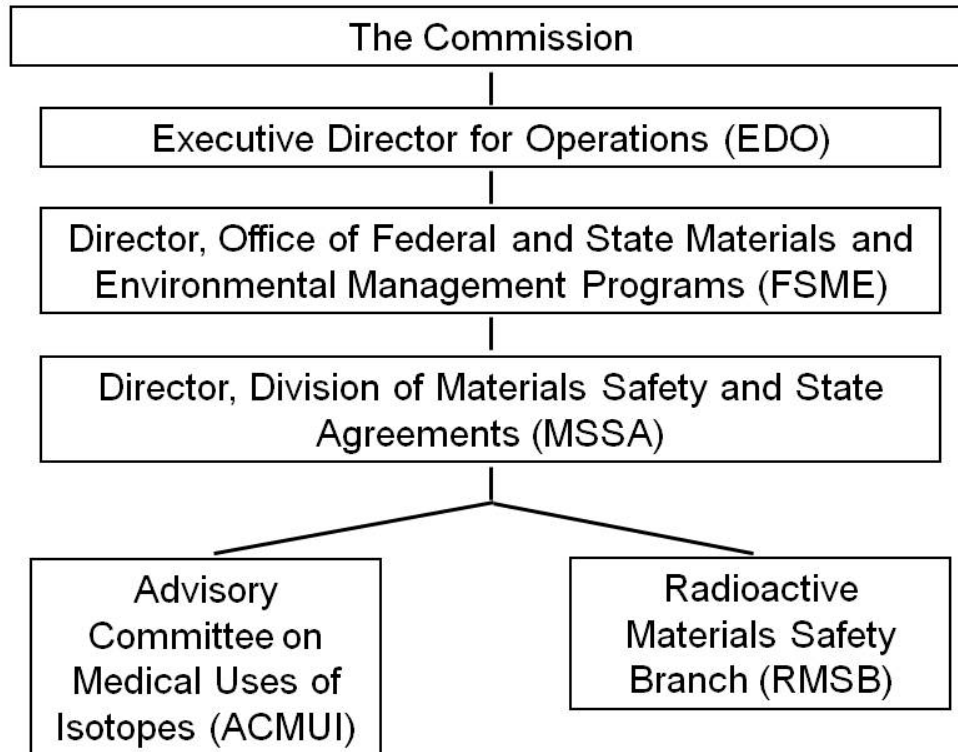
97 **Pp 2-3, § 1.2 Lines 6 and 7** For the same reason for the suggested revisions to § 1.1.6,
98 and 1.1.7, we suggest the word, “will,” be changed to,
99 “should.”
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101 **Pg 3, § 1.3.1 Line 1** The phrase, “All ACMUI meetings...,” should be changed to,
102 ““All ACMUI meetings and ACMUI Sub-Committee
103 meetings...”
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105 **Pg 5, § 4.2 Lines 3-4** This section states that. “The hours shall be transmitted via
106 email to the time resource inbox at
107 ACMUI_MedConsultTime.Resource@nrc.gov.” Identification
108 of a specific hyperlink for submission of work hours seems
109 unnecessarily restrictive and potentially problematic (eg in the
110 event the hyperlink is changed). It is suggested, therefore,
111 that this statement be revised as follows, “The hours shall be
112 transmitted to the NRC in the manner specified by staff.”
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115 **2. Discuss, address, and make a recommendation for the ACMUI reporting structure**
116 **(MSSA director versus the Commission)**¹

117 At its teleconference of January 12, 2011 and its semi-annual meeting of September 20,
118 2012, the ACMUI recommended an annual review of its reporting structure. The current
119 ACMUI reporting structure is summarized in the figure below (provided by Ms. Sophie
120 Holiday, ACMUI Coordinator, Office of Federal and State Materials and Environmental
121 Management Programs (FSME)). The key issue remains whether there is a significant
122 benefit to be derived by the ACMUI reporting directly to the Commission rather than through
123 the Office of Materials Safety and State Agreements (MSSA), the FSME, and the Executive
124 Director for Operations (EDO). The consensus opinion of the ACMUI was that there was
125 perhaps a “theoretical” advantage for reporting of the ACMUI to the Commission (eg
126 unfiltered transmission of opinions from the ACMUI to the Commission). However, the
127 working relationship between the NRC and ACMUI remains excellent, the reporting structure
128 through NRC staff (see figure below) continues to function effectively, and the associated
129 logistical “overhead” associated with direct reporting to the Commission (eg the need for
130 more frequent meetings) did not and does not now justify any change in the ACMUI’s
131 reporting structure. This recommendation is predicated on the annual Commission Briefing
132 by the ACMUI and the annual review of its reporting structure remaining in place.

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¹ Relevant information is provided in Federal and State Materials and Environmental Management Programs (FSME) Policy and Procedures (P&P) 2-5, Revision 0 (January 12, 2011), entitled, “FSME Procedure for Interacting with the Advisory Committee on the Medical Uses of Isotopes During Development of Major Medical Issues.” This P&P defines and documents FSME staff guidance and procedures for interfacing with the ACMUI during the development of major medical policy issues including medical rulemakings that will be reviewed by the Commission.



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3. Discuss, address, and make a recommendation for the consideration of budgeting for an additional face-to-face meeting at Headquarters

At the present time, the ACMUI holds two face-to-face meetings annually at NRC Headquarters, one in the spring and one in the fall. This schedule provides ample opportunity for timely and in-depth discussion of issues within the purview of the ACMUI. Additional face-to-face meetings (ie more than two meetings annually) are therefore probably unnecessary. On the other hand, the two-day Agendas of the ACMUI face-to-face meetings are typically full, so eliminating one such meeting per year would be counterproductive and impractical (especially considering recurring administrative tasks such as annual ethics and security training required of the Committee membership). Further, holding regularly scheduled meetings at 6-month intervals serves to maintain the timeliness of ACMUI deliberations; less frequent meetings (ie once a year) would likely result in new and pressing issues remaining unaddressed for a considerable period of time. (An example of just such an issue was the CardioGen-82 rubidium-82 generator breakthrough issue in 2011.) Another option, of course, is to replace one or both face-to-face meetings at Headquarters with web-based conferences (through Webex™ or Go-to-Meeting™, for example). This, too, would undermine the effectiveness of the Committee. The ACMUI membership consists of individuals with many time-critical day-to-day responsibilities at their respective institutions. It is difficult, if not impossible, to completely divest one's self of those responsibilities for several days at a time when physically present at one's home institution. Inevitably, participants in such a web-based conference would be diverted from the meeting at some point to attend to some pressing local issue. Furthermore, in contrast to face-to-face meetings, it is difficult in a web-based scenario to promote the spirit of collegiality and camaraderie among the participants that, in turn, promotes frank, constructive discussion. This is especially important for newer ACMUI members. It is logistically difficult as well to promote such discussion, since the Chair may

163 not be able to recognize Committee members wishing to speak in a timely manner, for
164 example. The Sub-Committee therefore recommends maintaining the current ACMUI
165 schedule of two face-to-face meetings annually at NRC Headquarters.
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168 **4. Consider the feasibility of conducting meetings using the Go-To-Meeting™ or Go-To-**
169 **Webinar™ function**

170 Web-based conferencing (through Webex™ or Go-to-Meeting™, for example) is now a
171 mature, reliable, universally available, inexpensive, and easy-to-use technology. It is
172 adaptable not only to desk and laptop PCs but also all mobile devices. Web-based
173 conferencing provides the obvious advantages of direct, real-time audio and video
174 communication among multiple individuals throughout the world, dramatic savings in time
175 and money with respect to travel, convenience, and flexible scheduling. It not only allows
176 display of any one of the attendee's computer screen to all other attendees of a conference
177 but also remote control by any one of the attendees of another attendee's computer and its
178 display. It is therefore far superior to conventional teleconferencing, which is restricted, of
179 course, to audio communication, and is especially useful for real-time editing of documents
180 through its common-display functionality. Web-based conferencing is therefore a potentially
181 important complement to face-to-face meetings. As discussed above, however, it is not a
182 viable replacement altogether for face-to face meetings. Inevitably, prolonged, dedicated (ie
183 interrupted) discussion is required to address the complex issues which often confront the
184 ACMUI, and such discussion is not realistically achievable via web-based conferencing.
185 The Sub-Committee therefore endorses the use of web-based conferences as needed as a
186 supplement to, but not as a replacement for, face-to-face meetings.