

2013 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
1	ACMUJ recommended NRC staff allow use of total source strength as a substitute for total dose for determining medical events for permanent implant brachytherapy until the Part 35 rulemaking is complete.	3/5/13	NRC Action	Closed 3/7/18
2	ACMUJ recommended that NRC staff solicit feedback from stakeholders, in Supplementary Information section IV.D, on whether the proposed ME definition for permanent implant brachytherapy would discourage licensees from using this form of therapy. This recommendation was modified the caveat that NRC may utilize the language that they think is appropriate for gaining this type of information from its stakeholders	3/5/13	NRC Action	Closed 3/7/18
3	ACMUJ recommended the draft rule re-defining medical events in permanent implant brachytherapy be designated as Compatibility Category B.	3/5/13 3/12/13	NRC Action	Closed 3/7/18
4	ACMUJ recommended replacing the phrasing in the literature in terms of support for the 5 cubic centimeters of contiguous normal tissue provision of the ME definition, to the specific reference cited as, Nag, et al 2004	3/5/13	NRC Action	Closed 3/7/18
5	ACMUJ recommended that licensees approved to use generator systems show specific training on the requirement now listed under 35.290 (c)(1)(ii)(G) for those individuals (Authorized Users and others) who are responsible for proper operation and testing of the generator as part of their license conditions. ACMUI further recommended that Authorized Nuclear Pharmacists who have the adequate training and experience (T&E) are able to provide the supervised work experience for Authorized Users on the elution of generators.	3/5/13	NRC Action	Closed 3/7/18

2013 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
			NRC Action	Closed
6	ACMUI endorsed the language in the proposed rule for preceptor attestations that states a candidate is able to independently fulfill the radiation safety related duties for which authorization is being sought.	3/5/13	NRC Action	Closed 3/7/18
7	ACMUI recommended that the work experience for parenteral administrations under Sections 35.390 (b)(1)(2)(g), and 35.396 not be separated between parenteral administrations of a beta gamma emitting radiopharmaceutical versus an alpha emitting radiopharmaceutical, as proposed in the proposed rule.	3/12/13	NRC Action	Closed 3/7/18
8	ACMUI recommended that the date of recognition of a certifying board should not impact individuals seeking to be named as an Authorized User, Authorized Radiation Safety Officer, Authorized Medical Physicist, or Authorized Nuclear Pharmacist through the certification pathway.	3/12/13	NRC Action	Closed 3/7/18
9	ACMUI recommended that the NRC adopt the FDA approved package insert for breakthrough limits for radioisotope generators	3/12/13	NRC Action	Closed 3/7/18
10	ACMUI recommended licensee reporting of out-of-tolerance generator breakthrough results to the NRC	3/12/13	NRC Action	Closed 3/7/18
11	ACMUI recommended requiring testing of molybdenum breakthrough on every elution of a molybdenum-technetium generator, rather than after only the first elution.	3/12/13	NRC Action	Closed 3/7/18
12	ACMUI recommended that the addition of Associate Radiation Safety Officers (ARSOs), and Temporary RSOs also be included in these exemptions in the same manner as AUs, ANPs, and AMPs.	3/12/13	NRC Action	Closed 3/7/18

2013 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS
13	In reference to the plain language requirement, the ACMUI suggested that the rule “could be shortened and improved by eliminating redundancies and consolidating related sections and eliminating identical or nearly identical passages appearing multiple times throughout the draft rule. A further improvement would be the inclusion of a detailed “executive summary”-style section summarizing, perhaps in a bullet format, the key changes introduced in the draft rule.”	3/12/13	NRC Action Closed 3/7/18
14	ACMUI recommended approval of the Second Draft ACMUI Rulemaking Subcommittee Report (ML 13071A690) with the caveat that all modifications discussed during the teleconference would be incorporated before submission to NRC staff.	3/12/13	NRC Action Closed
15	The ACMUI recommended tabling the discussion of amendments to the ACMUI Bylaws to the Fall 2013 ACMUI Meeting.	4/15/13	NRC Action Closed
16	Dr. Langhorst requested if NRC staff could add the Draft Guidance for the Draft Expanded Part 35 Rulemaking into the same docket number as the Rulemaking document. If this is not possible, she requests that the location (docket number) of the draft guidance be clearly identified in the Draft Expanded Part 35 Rulemaking docket and vice versa.	4/15/13	NRC Action Closed
17	The ACMUI have planned to hold a summer teleconference to discuss the Medical Events Subcommittee analysis of Yttrium-90 microspheres medical events. The dates are June 18, 2013 from 2-4pm EDT or June 20, 2013 from 2-4pm EDT (back-up).	4/15/13	ACMUI Action Closed
18	The ACMUI endorsed the Abnormal Occurrence Criteria Subcommittee Report.	4/15/13	ACMUI Action Closed
19	The ACMUI have planned to hold the Fall 2013 ACMUI Meeting at NRC Headquarters on September 9-10, 2013 or September 16-17, 2013 (back-up).	4/16/13	ACMUI Action Closed
20	Dr. Guiberteau requested that NRC staff provide a link to the abstract cited in Ms. Weill's ThyCa presentation to the full ACMUI.	4/16/13	NRC Action Closed

2013 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
21	The ACMUI recommended that NRC provides regulatory relief from the decommissioning funding plan requirements for the use of a Germanium-68/Gallium-68 generator.	4/16/13	NRC action	Closed
22	The ACMUI endorsed the Draft ACMUI Yttrium-90 Microsphere Brachytherapy Medical Events Analysis Report (ML 13162A113).	6/18/13	ACMUI Action	Closed
23	Dr. Thomadsen added Dr. Christopher Palestro to the Medical Events Subcommittee. Dr. Palestro will review the I-131 medical events. Subcommittee Members: Welsh (Chair), Langhorst, Mattmuller, Suh, Suleiman, Thomadsen	9/9/13	ACMUI Action	Closed
24	Dr. Thomadsen created a subcommittee to review the Proposed Amendments to the ACMUI Bylaws. The recommendations will be presentation in the spring 2014 meeting. Subcommittee members include: Dr. Chris Palestro, Dr. John Suh, Dr. Orhan Suleiman, Ms. Laura Weil, and Dr. Pat Zanzonico (chair).	9/9/13	ACMUI Action	Closed
25	The ACMUI recommended to reestablish the Rulemaking Subcommittee to review and address staff's response to the subcommittee's recommendations for the draft proposed expanded 10 CFR Part 35 Rulemaking.	9/10/13	ACMUI Action	Closed
26	Dr. Thomadsen added Mr. Steve Mattmuller to the ACMUI Bylaws Subcommittee	9/10/13	ACMUI Action	Closed
27	Dr. Thomadsen added the following additional charges to the ACMUI Bylaws Subcommittee: 1) Discuss, address and make a recommendation for the reporting structure (to the MSSA Director versus the Commission); 2) Discuss, address, and make a recommendation for the consideration of budgeting for an additional face-to-face meeting at Headquarters; 3) Consider the feasibility of conducting meetings using the Go-To-Meeting or Go-To-Webinar function.	9/10/13	ACMUI Action	Closed

2013 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS
28	Dr. Thomadsen requested that staff provide the Committee with the SECY Paper transmitted to the Commission in 2011 that discussed the pros and cons of restructuring the reporting structure of the ACMUI.	9/10/13	NRC Action Closed
29	Dr. Welsh recommended to add the topic of physical presence requirements of Authorized Users for the Gamma Knife and Perfexion for discussion at the spring 2014 meeting.	9/10/13	ACMUI Action Closed
30	The ACMUI planned the spring 2014 meeting for May 8-9, 2013. The back-up dates are May 12-13, 2013.	9/10/13	ACMUI Action Closed