

2015 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
			ACMUI Action	Closed
1	Mr. Costello and Dr. Langhorst will distribute questions to the Committee regarding the proper platform, expected and necessary participants, and feasibility of conducting an additional Medical Meeting.	03/19/2015	ACMUI Action	Closed
2	Dr. Thomadsen formed a subcommittee to review and evaluate the phrase "patient intervention". Members include: Dr. Dilisizian (Chair), Dr. Alderson, Mr. Costello, Dr. Ennis, Dr. Suh, and Ms. Weil. The NRC staff resource is Dr. Gabriel.	03/19/2015	ACMUI Action	Closed
3	Dr. Thomadsen formed a subcommittee to review the existing 10 CFR 35.1000 licensing guidance for radioactive seed localization. The subcommittee was tasked with making recommendations for revisions to the guidance. Members include: Dr. Ennis (Chair), Dr. Alderson, Mr. Costello, Dr. Zanzonico and Dr. Mettler (pending security clearance). A public teleconference will be held within the next several months. NRC staff resource is Ms. Holiday.	03/19/2015	ACMUI Action	Closed
4	Dr. Thomadsen added Dr. Ennis, Dr. O'Hara, and Dr. Zanzonico to the standing ACMUI Medical Events Subcommittee. Members include: Dr. Ennis (Chair), Dr. Langhorst, Mr. Mattmuller, Dr. O'Hara, Dr. Palestro, Dr. Suh, Dr. Thomadsen, and Dr. Zanzonico.	03/19/2015	ACMUI Action	Closed

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5	<p>Dr. Thomadsen has tasked the Ge/Ga-68 subcommittee with (1) estimating the number of potential Ge/Ga-68 generator licensees and (2) making a recommendation to the Committee on which route of action it believes NRC should pursue to address the decommissioning funding plan issue. The subcommittee should plan to hold a public teleconference within the next several months. Members include: Mr. Mattmuller (Chair), Mr. Costello, Dr. Langhorst, Dr. Palestro, and Dr. Zanzonico. NRC staff resource is Ms. Holiday.</p>	03/19/2015	<p>ACMUI Action</p> <p>Closed</p>
6	<p>Dr. Thomadsen will draft a letter to the Commission addressing the miswording of the intention of the ACMUI's recommendation for the ME Compatibility Category. The Committee's recommendation was to address the compatibility category for permanent implant brachytherapy only.</p>	03/20/2015	<p>ACMUI Action</p> <p>Closed</p>
7	<p>The ACMUI recommended that events reportable under 10 CFR 35.3047 that do not result in harm to the embryo/fetus/or nursing child not be captured as AO's reported to Congress.</p>	03/20/2015	<p>ACMUI Action</p> <p>Closed 3/7/18</p>
8	<p>The ACMUI will hold its Fall 2015 Meeting at NRC Headquarters on October 8-9, 2015. The back-up date is September 10-11, 2015.</p>	03/20/2015	<p>ACMUI Action</p> <p>Closed</p>

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9	Dr. Thomadsen created a subcommittee to evaluate if the required 700 hours for training and experience for authorized users of alpha and beta emitters places hardship on the patient community. If so, the subcommittee should make recommendations for potential changes (rulemaking). Subcommittee members include: Dr. Dilsizian, Dr. Ennis, Dr. Langhorst, Dr. Palestro (Chair), Ms. Weil, and Dr. Zanzonico. The subcommittee will present their draft report at the fall 2015 ACMUI Meeting scheduled to take place on October 8-9, 2015, at NRC Headquarters.	06/16/15	ACMUI Action Closed
10	The ACMUI Radioactive Seed Localization Subcommittee will revise their draft report and will present the final draft report at the fall 2015 ACMUI Meeting.	06/16/15	ACMUI Action Closed
11	The ACMUI endorsed the Germanium-68 Decommissioning Funding Plan Report (with addendum).	8/12/15	ACMUI Action Closed
12	The ACMUI recommended to make the following change to the Patient Intervention Subcommittee Recommendation Issue II: Unintentional Treatment outcome due to anatomic or physiologic anomaly and/or imaging uncertainty falls into the category “the Art of Medical Practice” provided that the standards of medical practice are met.	10/8/15	ACMUI Action Closed 3/7/18
13	The ACMUI endorsed the Patient Intervention Subcommittee Report with the modification to Issue II (listed in item 12 above).	10/8/15	ACMUI Action Closed 3/7/18

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14	Dr. Thomadsen requested that staff provide an update at the Spring 2016 ACMUI Meeting on staff response/action to the Patient Intervention Subcommittee Report.	10/8/15	NRC Action	Closed
15	The ACMUI recommended that staff issue a Generic Communication (i.e. Information Notice or Regulatory Issue Summary) to licensees to inform them of the interpretation of "patient intervention."	10/8/15	NRC Action	Closed 3/7/18
16	Dr. Thomadsen charged the Training and Experience (T&E) for Alpha and Beta Emitters Subcommittee with establishing a recommendation for the total number of hours of T&E for authorized users of such emitters, that is necessary for safety.	10/8/15	ACMUI Action	Closed
17	Dr. Ennis recommended that the individual who implants the source for radioactive seed localization be the authorized user only - and not an individual under the supervision of an authorized user. [Note: <i>the motion did not pass</i>]	10/8/15	ACMUI Action	Closed
18	The ACMUI recommended that the individual who implants the source for radioactive seed localization procedures can do so under the supervision of an authorized user.	10/8/15	Accepted	Closed
19	The ACMUI endorsed the Radioactive Seed Localization Subcommittee Report.	10/8/15	ACMUI Action	Closed

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			ACMUI Action	Closed
20	The ACMUI endorsed the Yttrium-90 Microspheres Subcommittee Report.	10/8/15	ACMUI Action	Closed
21	The ACMUI have planned the Spring 2016 Meeting for March 17-18, 2016. The back-up date is March 3-4, 2016.	10/9/15	ACMUI Action	Closed
22	The ACMUI endorsed the 2015 Abnormal Occurrence Criteria Subcommittee Report with the caveat that the report be amended to include an introductory paragraph that provides the rationale for the recommendations, as well as a summary paragraph to state that the Committee desires that the recommendations be incorporated into this revision of the NRC's Abnormal Occurrence Criteria Policy Statement.	10/9/15	ACMUI Action	Closed 3/7/18
23	The ACMUI endorsed the NUREG-1556, Volume 9 Subcommittee Report.	10/9/15	ACMUI Action	Closed
24	Dr. Thomadsen formed a subcommittee to proposed appropriate criteria for Medical Event Reporting for events other than permanent implant brachytherapy. Subcommittee members include: Dr. Dilisizian, Dr. Ennis, Mr. Ouhib, Dr. Palestro, Dr. Suh (Chair), and Dr. Zanzonico. The subcommittee will present its recommendations at the spring 2016 meeting. NRC staff resource: Dr. Katie Tapp	10/9/15	ACMUI Action	Closed