

2014 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS
1	<p>Dr. Thomadsen created a subcommittee to review the NRC Medical Policy Statement. The subcommittee was charged with determining if the Policy Statement needed revision(s). In addition, the subcommittee was asked to address the following two questions: 1) Stakeholders in the medical community have suggested that physicians are not performing permanent implant brachytherapy procedures because of NRC's current regulations in 10 CFR Part 35. Does the subcommittee believe this to be true; and 2) Does the subcommittee believe the regulations in 10 CFR Part 35, as amended in the proposed rule, address this real or perceived issue? Subcommittee members include: Dr. Thomadsen (chair), Dr. Guiberteau, Dr. Palestro, and Dr. Suh.</p>	1/30/14	<p>ACMUI Action</p> <p>Closed</p>
2	<p>Dr. Thomadsen added Dr. Philip Alderson to the Medical Policy Statement Subcommittee.</p>	3/24/14	<p>ACMUI Action</p> <p>Closed</p>
3	<p>The ACMUI recommended to endorse the Medical Policy Statement Subcommittee Report. This included a recommendation to make no changes to the current Medical Policy Statement.</p>	5/8/14	<p>ACMUI Action</p> <p>Closed</p>
4	<p>Dr. Thomadsen formed a subcommittee to review the medical event reporting criteria of the yttrium-90 microspheres (35.1000) guidance. Subcommittee members include: Dr. Guiberteau (chair), Mr. Costello, Dr. Langhorst, Dr. Palestro, Dr. Thomadsen, and Dr. Welsh. The subcommittee will present their recommendations at the Fall 2014 meeting. The NRC staff resource is Dr. Howe.</p>	5/8/14	<p>ACMUI Action</p> <p>Closed</p>
5	<p>Dr. Thomadsen added Mr. Frank Costello to the Medical Events Subcommittee.</p>	5/8/14	<p>No Action Required</p> <p>Closed</p>
6	<p>Dr. Thomadsen formed a subcommittee on May 8, 2014 to provide staff with the background information to justify the recommendation for the regulatory relief from the DFP of Ge-68. The subcommittee is specifically charged with evaluating the cost of a DFP for the use of Ge-68, its effect on the future clinical use of new Ga-68 radiopharmaceuticals and how appropriate regulatory relief may be gained. Subcommittee members include Mr. Mattmuller (chair), Dr. Langhorst, Mr. Costello, Dr. Palestro and Dr. Zanzonico.</p>	5/8/14	<p>ACMUI Action</p> <p>Closed</p>

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7	Staff will provide the Ge-68 DFP Subcommittee with the NRC guidelines for developing a Regulatory Basis.	5/8/14	NRC action	Closed
8	The ACMUI will hold the fall 2014 ACMUI Meeting in T2-B3 on September 29-30, 2014. The back-up date is October 20-21, 2014.	5/9/14	NRC action	Closed
9	The ACMUI recommended to table the discussion and vote on the revisions to the ACMUI Bylaws until the September 29-30, 2014 meeting.	8/20/14	ACMUI Action	Closed
10	The ACMUI recommended that the total treatment activity of yttrium-90 microspheres to be administered should be the required compliance measure for organs and tissues other than the treatment site.	9/29/14	NRC action	Closed
11	The ACMUI recommended that the implantation of the microsphere brachytherapy sources is considered to be in accordance with the written directive if the total administered/infused activity does not vary from the activity prescribed in the written directive by 20% or more; except in situations in which the activity administered is limited by the termination of procedure due to stasis.	9/29/14	NRC action	Closed
12	The ACMUI recommended that (a) these recommendations be incorporated into the NRC guidance for yttrium-90 microsphere brachytherapy and that (b) the NRC staff, in consultation with ACMUI, compose and disseminate explanation of these recommended revisions in a manner best suited to both the NRC as well as to AUs and other stakeholders tasked with compliance.	9/29/14	NRC action	Closed

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13	The ACMUI endorsed the yttrium-90 microsphere brachytherapy medical event reporting criteria subcommittee report.	9/29/14	ACMUI Action	Closed
14	The ACMUI endorsed the revisions to the ACMUI Bylaws presented on September 29, which includes the proposed language in section 1.3.5 and 3.1 and changes to reflect the new office structure.	9/29/14	ACMUI Action	Closed
15	The ACMUI requested that staff provide them with a contact list for the NRC Commissioners.	9/29/14	NRC action	Closed
16	Ms. Holiday committed to providing the memorandum sent to the Commissioners regarding the international practices of patient release.	9/29/14	NRC action	Closed
17	Dr. Thomadsen tasked Dr. Langhorst and Mr. Costello with creating a proposal to present to the Committee and staff regarding the costs and logistics for an additional face-to-face meeting and/or a medical regulatory information conference.	9/29/14	ACMUI Action	Closed
18	The ACMUI have tentatively scheduled the Spring 2015 Meeting for March 19-20, 2015. The back-up date is March 24-25, 2015	9/30/14	ACMUI Action	Closed
19	Dr. Thomadsen formed a subcommittee to review the advanced notice of proposed rulemaking for Title 10 Code of Federal Regulations Part 20, "Standards for Protection Against Radiation." Subcommittee members include: Dr. Langhorst (chair), Mr. Costello, Dr. Dilisizian, Mr. Mattmuller, and Dr. Zanzonico. The subcommittee will present their recommendations at a future teleconference.	9/30/14	ACMUI Action	Closed

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20	<p>Dr. Thomadsen tasked Dr. Suh and Dr. Welsh to work with the American Society for Radiation Oncology for their proposed changes to the language in the Draft FY15 Water and Energy Bill. Dr. Ennis will serve as a consultant to Drs. Suh and Welsh until he assumes the role of the ACMUI's Brachytherapy Radiation Oncologist in February 2015. Drs. Ennis, Suh, and Welsh will present the language to the Committee at the spring 2015 meeting.</p>	9/30/14	<p>ACMUI Action</p> <p>Closed</p>
21	<p>The ACMUI endorsed the ANPR for Part 20 subcommittee report.</p>	12/10/14	<p>ACMUI Action</p> <p>Closed</p>