2007 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
2	NRC staff should remove the attestation requirement for board certified individuals and rewrite the attestation requirement for individuals seeking authorization under the alternate pathway. The rewritten attestation should not include the word “competency” but should instead read “has met the training and experience requirements.”	6/12/07	Accepted	Open
3	NRC staff should revise the regulations so that board certified individuals, who were certified prior to the effective date of recognition or were certified by previously recognized boards listed in Subpart J of the previous editions of Part 35, are grandfathered.	6/12/07	Accepted	Open
6	NRC staff should add the words “or equivalent” so it is clear that information included in a letter is the same as that which would have been submitted in NRC Form 313A (35.12(c))	6/13/07	Accepted	Open
7	NRC staff should revise 10 CFR 35.50(c)(2) to include AUs, AMPs, or ANPs identified on any license or permit that authorizes similar types of use of byproduct material. Additionally, the AU, AMP, or ANP must have experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking RSO authorization.	6/13/07	Accepted	Open
8	NRC staff should remove the attestation requirement from 10 CFR 35.50(d) for AUs, AMPs, and ANPs seeking RSO status, if the AU, AMP, or ANP seeking RSO status will have responsibilities for similar types of uses for which the individual is authorized.	6/13/07	Accepted	Open
10	a) NRC staff should allow more than one RSO on a license with a designation of one RSO as the individual in charge. b) NRC should create a Regulatory Issue Summary (RIS) to inform the regulated community of NRC’s interpretation. The RIS should be sent to ACMUI and the Agreement States for review and comment.	6/13/07	a) Accepted b) Accepted	a) Open b) Closed
25	NRC staff should revise the current regulations to include Canadian trained individuals who have passed the ABNM certification exam.	8/16/07	Accepted	Open
30	The Elekta Perfexion® should be regulated under 10 CFR 35.1000 until 10 CFR 35.600 is modified to be performance-based, which would allow the Perfexion® to be regulated under 10 CFR 35.600.	10/22/07	Accepted	Open *Delayed*
31	NRC staff should require experienced RSOs and AMPs to receive additional training, if the individual is seeking authorization or responsibility for new uses.	10/22/07	Accepted	Open
32	NRC staff should not require experienced RSOs to obtain written attestation to become authorized or have responsibility for new uses.	10/22/07	Accepted	Open
34	NRC staff should modify 10 CFR 35.491(b)(2) to specify 'superficial’ ophthalmic treatments. Additionally, NRC staff should change the title of 10 CFR 35.491 to specify ‘superficial’ ophthalmic treatments.	10/22/07	Accepted	Open *Delayed*
35	NRC staff should not revise 10 CFR 35.491 (intended for ophthalmologists) to include training and experience for the new intraocular device. Instead, NRC staff should regulate the new intraocular device under 10 CFR 35.490.	10/22/07	Partially Accepted	Open *Delayed*
36	NRC staff should not require medical licensees regulated under 10 CFR 35.400, 500, or 600, as applicable, to only use the sealed sources and devices for the principle use as approved in the SSDR.	10/22/07	Accepted	Open
37	NRC staff should revise 10 CFR 35.290 to allow physicians to receive training and experience in the elution of generators and preparation of kits under the supervision of an ANP.	10/22/07	Accepted	Open

2008 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
2	NRC staff should pursue rulemaking to allow more than one RSO on a medical use license with the indication of one RSO as the individual in charge.	4/28/08	Accepted	Open
5	NRC staff should incorporate the subcommittee's recommendations for the Gamma Knife® Elekta Perfexion™ in future rulemaking.	4/28/08	Accepted	Open *Delayed*
9	NRC staff should revise the AO criteria to read, "A medical event that results in: 1) death; or 2) a significant impact on patient health that would result in permanent functional damage or a significant adverse health effect that would not have been expected from the treatment regimen, as determined by an NRC or Agreement State designated consultant physician."	4/28/08	Accepted	Open
19	NRC staff should accept the six recommendations of the Permanent Implant Brachytherapy Subcommittee report with one modification. Recommendation six should be modified to read, "When a Written Directive (WD) is required, administrations without a prior WD are to be reported as regulatory violations and may or may not constitute an ME."	10/27/08	Pending	Open *Delayed*
22	ACMUI encouraged NRC staff to begin the rulemaking process to move the medical use of Y-90 microspheres from 10 CFR 35.1000 to another section of the regulations, so that the training and experience requirements for AUs can be vetted though the public review process instead of residing in guidance space.	10/27/08	Partially accepted	Open
26	NRC staff should revise 10 CFR 35.40 to clarify that the AU should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs	10/28/08	Accepted	Open *Delayed*
27	NRC staff should revise 10 CFR 35.40 to clarify that an AU, not the AU, should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs. [Note this allows for one AU to sign the pre-implantation portion of the WD and another AU to sign the post-implantation portion of the WD]	10/28/08	Accepted	Open *Delayed*
28	NRC staff should revise 10 CFR 35.65 to clarify it does not apply to sources used for medical use; however, NRC should not require licensees to list the transmission sources as a line item on the license. NRC staff should also revise 10 CFR 35.590 to permit the use of transmission sources under 10 CFR 35.500 by AUs meeting the training and experience requirements of 10 CFR 35.590 or 35.290.	10/28/08	Accepted	Open
29	NRC staff should revise 10 CFR 35.204(b) to require a licensee that uses Mo 99/Tc-99m generators for preparing a Tc-99m radiopharmaceutical to measure the Mo-99 concentration of each eluate after receipt of a generator to demonstrate compliance with not administering to humans more than 0.15 microcurie Mo-99 per millicurie Tc-99m.	10/28/08	Accepted	Open
30	NRC staff should require licensees to report to the NRC events in which licensees measure molybdenum breakthrough that exceeds the regulatory limits.	10/28/08	Accepted	Open

2009 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
2	NRC staff should revise 35.390(b)(1)(ii)(G)(3) to read "parenteral administration requiring a written directive for any radionuclide that is being used primarily because of its beta emission, or low energy photo-emission, or auger electron; and/or" and revise 35.390(b)(1)(ii)(G)(4) to read "parenteral administration requiring a written directive for any radionuclide that is being used primarily because of its alpha particle emission"	5/7/09	Accepted	Open
9	Dr. Malmud added three temporary members to the medical events subcommittee: Dr. Welsh (chair), Dr. Langhorst, Mr. Mattmuller. Existing subcommittee members inlcude: Ms. Gilley, Dr. Suleiman, and Dr. Thomadsen.	10/19/09	No NRC action	Open
10	ACMUI recommends NRC staff delete the phrase "at a medical institution" from 10 CFR 35.2, 35.490(b)(1)(ii), 35.491(b)(2) and 35.690(b)(1)(ii).	10/19/09	Accepted	Open

2010 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
17	ACMUI will provide a list of action items for NRC staff based on the recommendations provided in the Patient Release Subcommittee Report.	12/13/10	ACMUI Action	Closed 9/22/11	Lewis	

2011 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
1	ACMUI endorsed the draft response to NRC comments, as reflected in the meeting handout (ML110600249). ACMUI agreed if NRC believes the release criteria should be changed from a per release criteria to an annual criteria, this change would require new rulemaking, as stated in Regulatory Issue Summary (RIS) 2008-07. ACMUI recommended rulemaking to clarify that the release under 10 CFR 35.75 is per release and not per year	1/5/11	NRC action	Open	Langhorst/Gilley	9, 1, 0
6	ACMUI created an action item to reevaluate its satisfaction with the reporting structure annually.	1/12/11	ACMUI Action	Open indefinitely	Welsh/Zanzonico	
7	Dr. Malmud will serve as a reviewer to screen I-131 cases for the ACMUI Medical Event Subcommittee	4/11/11	ACMUI Action	Open indefinitely		
9	ACMUI recommended a 3 month (minimum) notice for future Public Stakeholder Workshop Meetings.	4/11/11	NRC action	Closed	Welsh/Thomadsen	11, 0, 0
10	ACMUI recommends NRC Staff hold the second Public Stakeholder Workshop in August in order to accommodate all public stakeholders, with the caveat that the ACMUI Permanent Implant Brachytherapy Subcommittee Report be finalized by the Fall ACMUI Meeting.	4/11/11	NRC action	Closed 2/7/12	Welsh/Thomadsen	
11	(1) ACMUI feels ASTRO's approach to Permanent Implant Brachytherapy (handout) is correct approach for patient welfare (2) ACMUI recommends that the NRC require Post-Implant dosimetry following brachytherapy treatment (3) ACMUI believes that prostate brachytherapy is a unique subset of brachytherapy and should therefore require a separate set of rules from non-prostate brachytherapy.	4/11/11	NRC action	Closed 2/7/12	Welsh/Mattmuller	11, 0, 0
12	ACMUI has planned to hold the Fall 2011 ACMUI Meeting on September 22 - 23, 2011. The back-up date is October 27 - 28, 2011. The alternate back-up date is October 31 -November 1, 2011	4/11/11	ACMUI Action	Closed 9/22/11		
13	ACMUI recommends to eliminate the written attestation for board certification pathway, regardless of date of certification	4/12/11	NRC action	Open	Zanzonico/Guiberteau	11, 0, 0
14	ACMUI recommends the attestation to be revised to say … has received the requisite training and experience in order to fulfill the radiation safety duties required by the licensee	4/12/11	NRC action	Open	Langhorst/Thomadsen	11, 0, 0
15	ACMUI supports the statement that residency program directors can sign attestation letters, representing consensus of residency program faculties, if at least one member of the faculty is an AU in the same category as that designated by the applicant seeking authorized status, and that AU did not disagree with the approval.	4/12/11	NRC action	Open	Thomadsen/Welsh	11, 0, 0

2011 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
16	ACMUI continues to assert that the current regulations are based on a per release limit. ACMUI does not recommend any change to the regulation and does not recommend the NRC consider this topic during the current rulemaking process, as there is no clinical advantage or advantage to members of the public for using an annual limit.	4/12/11	NRC action	Closed	Langhorst/Welsh	11, 0, 0
19	Steve Mattmuller asked that NRC Staff add ACMUI to the organizational chart on the FSME website.	9/22/11	NRC action	Open	Mattmuller	
20	Dr. Langhorst requested that NRC staff 1) place historical documents on the ACMUI website that would give everyone a better understanding of the ACMUI organization and how it got to where it is today and 2) NRC add past ACMUI membersip information on the ACMUI Website.	9/22/11	NRC action	Open	Langhorst	
21	Dr. Malmud created a subcommittee to address electronic signatures for documents licenees are required to retain in accordance with 10 CFR Part 35. Subcommittee members include: Dr. Bruce Thomadsen (chair), Dr. John Suh, Dr. Christopher Palestro, and Dr. James Welsh	9/22/11	ACMUI Action	Open	Thomadsen/Guiberteau	
22	ACMUI recommends to table the discussion on changes to the AO criteria	9/23/11	NRC action	Closed 12/15/11	Mattmuller/Langhorst	12, 0, 0
23	Dr. Leon Malmud added Dr. John Suh to the Permanent Implant Brachytherapy Subcommittee. Existing subcommittee members include: Dr. James Welsh (chair), Dr. Susan Langhorst, Dr. Orhan Suleiman, and Dr. Bruce Thomadsen	9/23/11	ACMUI Action	Open		
24	The Permanent Implant Brachytherapy Subcommittee will revise the subcommittee report and distribute to the full committee for review by October 7, 2011.	9/23/2011	ACMUI Action	Closed 10/18/11		
25	The ACMUI planned a teleconference for October 18, 2011, 12:00pm - 2:00pm EDT to discuss and finalize the Permanent Implant Brachytherapy Subcommitee Report.	9/23/2011	ACMUI Action	Closed 10/18/11		
26	NRC staff will provide an advanced copy of the Permanent Implant Brachytherapy Subcommitte report to the Agreement States prior to the ACMUI teleconference call and will invite the States to participate in the call.	9/23/2011	NRC action	Closed 10/18/11		
27	ACMUI has planned to hold the Spring 2012 ACMUI Meeting on April 16-17, 2012. Back-up dates are April 26-27, 2012.	9/23/11	ACMUI Action	Closed 4/16/12		
28	ACMUI recommends the language in item A1B of the PIBS Report to read as, "Within a timeframe to be determined by the Authorized User consistent with prevailing practice, but not to exceed 60 days unless accompanied by written justification."	10/18/11	ACMUI Action	Closed 10/18/11	Zanconico/Thomadsen	12,0,0

2011 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
29	ACMUI recomments to insert the following phrase into item 3B of the PIBS Report "using the wrong radionuclides or wrong activity or source strength (+/- 20%)" and moving the rest of the items down (from 3B to 3C and so forth)	10/18/11	ACMUI Action	Closed 10/18/11	Thomadsen/?	12,0,0
30	Dr. Zelac suggested to change the verbage in the PIB Report, Section A number 1(a)(i) from, "greater than 20 percent of the sources fall out of the intended locations." to "20 percent or more of the sources as called for in the Written Directive".	10/18/11	ACMUI Action	Closed 10/18/11		
31	Dr. Zelac suggested to change "Terminology," and specifically the definition that's given of D-90 to read as "the minimum dose to 90 percent of the CTV" in the PIBS Report.	10/18/11	ACMUI Action	Closed 10/18/11		
32	ACMUI reaffirms the 2008 AO Criteria as stated in the handout with the amendment that (s) be added to the end of physician, to read "consultant physician(s)"	12/15/11	NRC action	Open	Guiberteau/Mattmuller	11,0,1

2012 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
1	ACMUI recommended the following two changes to the PIBS Report: 1) the addition of the word "final" to the recommendation B, paragraph 1, the last sentence, to read as "in accordance with the final planned distribution." and 2) the word "(contiguously)" be dropped and, instead, using it as an adjective with the word "contiguous," preceding the "centimeters" in both subheadings 2(a) and 2(b).	2/7/12	ACMUI Action	Closed 2/7/12	Zanzonico/Welsh	11, 0, 1
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