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	Closed 3/7/18
3	NRC staff should promptly notify ACMUI members in a separate memo when an ACMUI recommendation is not accepted.	4/28/08	Accepted	Ongoing
4	ACMUI form a subcommittee, which includes*: Dr. Darrell Fisher, Mr. Ralph Lieto, Dr. Bruce Thomadsen (Chair), and Dr. Richard Vetter. The subcommittee's charge is to evaluate the efficacy and cost of cesium chloride versus current and proposed x-ray technologies and cobalt. The subcommittee will also evaluate security issues. *Dr. Malmud added the following members to the subcommittee on April 29, 2008: Ms. Debbie Gilley, Dr. Orhan Suleiman, and Dr. James Welsh.	4/28/08	No NRC action	Closed 10/13/08
5	NRC staff should incorporate the subcommittee's recommendations for the Leksell Gamma Knife® Elekta Perfexion™ in future rulemaking.	4/28/08	Accepted	Closed 3/7/18
6	Dr. Subir Nag suggested ACMUI form a subcommittee to discuss the permanent implant brachytherapy rulemaking. The subcommittee would include : Dr. Nag, Dr. Bruce Thomadsen, and Dr. James Welsh. The subcommittee could consult with other knowledgeable individuals, as necessary.	4/28/08	Motion did not pass	Closed

2008 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
7	Dr. Leon Malmud, ACMUI Chairman, requested NRC staff email Dr. Nag separately once the permanent implant brachytherapy proposed rule is published.	4/28/08	Accepted	Closed 8/7/08
8	NRC staff should arrange a public full Committee teleconferenced meeting in July to discuss the permanent implant brachytherapy rulemaking.	4/28/08	Accepted	Closed 7/21/08
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	Closed
10	NRC staff should incorporate the three hands-on, in-vitro, simulated cases approach as proposed during the meeting. Additionally, NRC staff should indicate when it is appropriate for a licensee to submit a license amendment to add the AU or Y-90 microspheres to the license. Lastly, NRC staff should add a statement to the guidance to require the manufacturer to proctor the first three cases performed by an AU.	4/29/08	Accepted	Closed 8/21/08
11	NRC staff should make all of the changes as proposed, except on page 2 the word "post-operative" should be replaced with "post-procedural."	4/29/08	Accepted	Closed 9/10/08
12	NRC staff should send an EDO daily note indicating the ACMUI discussed the Part 35 Implant Brachytherapy Rulemaking at the 7/21/08 ACMUI teleconference.	7/21/08	Accepted	Closed 7/24/08

2008 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
13	NRC staff should proceed with SECY-08-0080 and publish the proposed rule in the Federal Register, as directed by the Commission. (ACMUI will submit comments during the 75-day comment period.)	7/21/08	Accepted	Closed 8/6/08
14	ACMUI should form a subcommittee for the permanent implant brachytherapy rulemaking. The subcommittee's charge is to meet within the next two weeks to prepare ACMUI's comments on the proposed rulemaking. The subcommittee includes: Dr. Nag (chair), Mr. Lieto, Dr. Thomadsen, Dr. Vetter, and Dr. Welsh.	7/21/08	No NRC action	Closed 11/5/08
15	NRC staff should provide a status update on the technical basis for the Ritenour/AAPM petition at the October 2008 ACMUI meeting	7/21/08	Accepted	Closed 10/28/08
16	NRC staff should distribute request letters for information on the individuals impacted by the Ritenour/AAPM petition to the certifying boards as well as professional societies.	7/21/08	Accepted	Closed 10/08
17	NRC staff should allow the manufacturers to continue to use their current standards for proctoring the first three patient cases for new Authorized Users. For Sirtex, at least the first two cases will be proctored by a physician. For MDS Nordion, all three cases will be proctored by an MDS Nordion employee.	7/21/08	Accepted	Closed

2008 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
18	NRC staff agreed to consider incorporating the subcommittee's recommendations from the August 1, 2008 Fingerprinting Subcommittee Report in NRC's Questions and Answers with Regards to Fingerprinting and Criminal History Records Checks or use another appropriate method of communication to transmit the information to licensees.	10/27/08	Pending	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*
20	The ACMUI endorsed the permanent implant brachytherapy subcommittee report.	10/27/08	No NRC action	Closed 10/27/08
21	The ACMUI formed a subcommittee to draft a set of proposed qualifications that IRs must satisfy to become AUs for Y-90 microspheres. The subcommittee includes: Dr. Bruce Thomadsen (chair), Dr. Douglas Eggli, Dr. Subir Nag, Dr. James Welsh, and Mr. Steve Mattmuller.	10/27/08	No NRC action	Closed 5/8/09

	ITEM	DATE	STATUS	
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	Closed 3/7/18
23	The ACMUI strongly encourages NRC to: (1) continue supporting the exportation of HEU material for Mo-99 targets used by international producers; (2) provide all possible help towards the development of US producers of Mo-99.	10/28/08	Acknowledged	Closed 4/23/09
24	ACMUI formed a subcommittee to develop a solution that satisfies both the training needs of the residency program and the NRC requirements for achieving AU status using the board certification pathway. The subcommittee should create a recommendation to be discussed at a future teleconference prior to the spring 2008 ACMUI meeting. The subcommittee includes: Dr. Douglas Eggli (chair), Dr. Subir Nag, Dr. William Van Decker, and Dr. Mickey Guiberteau (technical assistance).	10/28/08	No NRC action	Closed 5/8/09
25	NRC staff should revise 10 CFR 30.35(b) to allow licensees to exceed the limits short term (e.g. 60 days) during source exchange.	10/28/08	Not Accepted	Closed 5/24/10

	ITEM	DATE	STATUS	
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	Closed 3/7/18

	ITEM	DATE	STATUS	
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	Closed 3/7/18
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	Closed 3/7/18