

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 Accepted	b) 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 <i>Delayed</i>
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 <i>Delayed</i>
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 <i>Delayed</i>
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 SDDR.	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
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	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 <i>Delayed</i>
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 through 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 <i>Delayed</i>
27	NRC staff should revise 10 CFR 35.40 to clarify that <u>an</u> AU, not <u>the</u> 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 <i>Delayed</i>
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	
1	NRC staff should allow IRs to become AUs for Y-90 microspheres with: 1) 80 hours training in: a) radiation physics & instrumentation; b) radiation protection; c) mathematics pertaining to the use and measurement of radioactivity; d) chemistry of byproduct material for medical use; and e) radiation biology; and 2) work experience under the supervision of an Authorized User involving: a) ordering, receiving, & unpacking radioactive materials safely & performing the related radiation surveys; b) checking survey meters for proper operation; c) examination of each individual; d) calculating, measuring, & safely preparing patient or human research subject dosages; e) using administrative controls to prevent a medical event involving the use of byproduct material; f) using procedures to control and to contain spilled byproduct material safely & using proper decontamination procedures; g) follow up and review of each patient's or human research subject's case history; and h) the operation of and quality management for dose calibrators; and 3) board certification in diagnostic radiology with a subspecialty in interventional radiology or three years supervised clinical experience in diagnostic radiology with one year in interventional radiology	5/7/09	Accepted	Closed 1/26/11
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
3	NRC staff should revise 10 CFR 35.490 & 690 as proposed with one exception. Delete "private practice." The regulation should read "500 hours of work experience, under the supervision of an Authorized User who meets the requirements in [35.490 or 35.690] or equivalent Agreement State requirements at a medical institution or clinic..."	5/7/09	Superseded by item 10	Closed
4	To prevent recurrence of events like those at the VA, ACMUI recommends: 1) Every brachytherapy quality assurance program include peer review as published by the American Brachytherapy Society and 2) Authorized Users should perform post-implant dosimetry	5/7/09	No NRC action	Tabled
5	ACMUI will create a subcommittee that includes three members to review ICRP Report 103 and get back to Dr. Don Cool	5/8/09	ACMUI Action	Closed
6	a) ACMUI came to a consensus on NCRP report 160, which is believed to be scientifically sound and well-written b) ACMUI believes NRC and Agreement States should collect and maintain dose records and keep ACMUI aware of the issues but should continue a policy of not intervening with medical practice c) ACMUI supports the medical principle of "First do no harm" and expressed continued concern about exposure to children d) ACMUI's current belief is that the benefit of medical procedures involving radiation outweighs the risk	5/8/09	No NRC action	Closed
7	ACMUI endorsed the subcommittee report for American Board of Radiology candidates who may experience a delay between the completion of Training and Experience and receipt of board certification	5/8/09	No NRC action	Closed
8	NRC staff should not require licensees to report therapeutic infiltrations as Medical Events.	5/8/09	*Not Accepted*	Closed
9	Dr. Malmud added three temporary members to the medical events subcommittee: Dr. Welsh (chair), Dr. Langhorst, Mr. Mattmuller. Existing subcommittee members include: 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
11	ACMUI recommends NRC staff revise 10 CFR 35.41(a) by adding "(3) If the administration is not in accordance with the written directive, a determination of whether it resulted in a reportable medical event will be made in a timely manner."	10/19/09	Motion did not pass	Closed

2010 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
1	Dr. Thomadsen created a subcommittee to evaluate patient release issues; to objectively review and analyze available data, which may include state regulations and guidance and international recommendations; to provide a statement on the issue; and to provide recommendations for improvements to existing NRC rules and guidance, if necessary, which should include the issue of patient release to hotels. Subcommittee members include: Dr. Darrell Fisher, Ms. Debbie Gilley, Dr. Susan Langhorst (chair), Mr. Steve Mattmuller, Dr. Orhan Suleiman, Dr. Bruce Thomadsen, Dr. James Welsh, Dr. Pat Zanzonico. The subcommittee should report to the full ACMUI at the fall meeting.	5/24/10	ACMUI Action	Closed 12/13/10	Welsh/Fisher	8, 0, 0
2	The Permanent Implant Brachytherapy subcommittee will revise the draft subcommittee report and resubmit it to the full ACMUI for an email vote. The ACMUI will submit a final subcommittee report to the NRC.	5/24/10	ACMUI Action	Open	Zanzonico/Gilley	8, 0, 0
4	NRC staff should revise the Y-90 microsphere brachytherapy guidance to delete "but before the patient or human research subject leaves the post-procedure recovery area" under item 2 of the written directive section.	5/25/10	Partially accepted	Closed 1/26/11	Welsh/Zanzonico	8, 0, 0
5	NRC staff should revise the Y-90 microsphere brachytherapy guidance to read (under 1 for written directives) "and, if the procedure was not performed in accordance with the pre-administration written directive", then 2) "after administration and within 48 hours of the procedure, the signature of an AU."	5/25/10	Partially accepted	Closed 1/26/11	Welsh/Zanzonico	8, 0, 0
6	NRC staff should consider the necessity and evaluate options to collect or obtain data for the denominator for medical events to improve the overall value of the medical events subcommittee report.	5/25/10	Accepted	Closed 3/1/11	Lewis	
9	ACMUI endorses the permanent implant brachytherapy subcommittee report with the caveat that this is an interim report that may be revised in the future to consider additional input such as that received from stakeholders at public workshops.	10/20/10	Accepted	Closed 12/22/10	Welsh/Gilley	10, 0, 0
10	ACMUI endorses the draft version of FSME Policy and Procedures 2-5, Revision 0 presented at the meeting.	10/21/10	Accepted	Closed 1/21/11	Langhorst/Fisher	10, 0, 0
11	Dr. Thomadsen created a subcommittee to prepare a document to guide the December discussion on 10 CFR Part 37. Debbie Gilley (chair), Susan Langhorst, Darrell Fisher.	10/21/10	ACMUI Action	Closed 1/5/11	Thomadsen	
12	ACMUI will incorporate the comments made during the meeting to revise the patient release subcommittee report. The committee will vote to finalize the report via email and will resubmit it to NRC in the near future.	10/21/10	ACMUI Action	Closed 12/13/10	Thomadsen	
13	Steve Mattmuller, Bruce Thomadsen, and Susan Langhorst offered to provide support to respond to the letter dated October 20, 2010, to Chairman Jaczko from Congressman Markey regarding patient release.	10/21/10	ACMUI Action	Open	Thomadsen	
14	ACMUI planned a teleconference to discuss 10 CFR Part 37 rulemaking and safety culture on Monday, December 13, 2010, from 1:00 pm to 3:00 pm Eastern. The backup time/date is Wednesday, December 15, 2010 from 11:00 am to 1:00 pm Eastern.	10/21/10	ACMUI Action	Closed 12/13/10	Thomadsen	
15	ACMUI endorsed draft Policy and Procedure 2-5 with comments, as reflected in the meeting handout.	12/13/10	Partially accepted	Closed 1/12/11	Thomadsen/Gilley	10, 0, 0

2010 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
16	ACMUI approved the Patient Release Subcommittee Report, as reflected in the meeting handout.	12/13/10	Accepted	Closed 12/13/10	Welsh/Fisher	10, 0, 0
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	Open	Lewis	
18	ACMUI deferred their discussion on the draft final safety culture policy statement to the January 2011 teleconference.	12/13/10	ACMUI Action	Closed 1/5/11	Guiberteau/Gilley	10, 0, 0
19	The ACMUI will develop a draft document on rulemaking and implementation guidance for physical protection of byproduct material for further discussion at a January 2011 teleconference.	12/13/10	ACMUI Action	Closed 1/5/11	Gilley	

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
2	ACMUI recommended NRC staff maintain the current reporting structure for the Committee; however, the motion was tabled for further discussion at the January 12, 2011 ACMUI Teleconference	1/5/11	ACMUI Action	Closed 1/12/11	Welsh/Zanzonico	
3	ACMUI endorsed the draft comments on proposed 10 CFR Part 37, as reflected in the meeting handout (ML110600261)	1/5/11	NRC action	Open	Gilley/Suh	10, 0, 0
4	ACMUI endorsed the Draft Final Safety Culture Policy Statement	1/5/11	Accepted	Closed 1/26/11	Thomadsen/Fisher	9, 1, 0
5	ACMUI recommended NRC staff maintain the current reporting structure for the ACMUI with enhancements in communication as described in FSME Policy and Procedure 2-5 and increased technical and administrative support staff.	1/12/11	Accepted	Open	Guiberteau/Langhorst	10, 0, 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	
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