

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 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 SDR.	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	Open
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
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	
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	No NRC action	Open
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	No NRC action	Open
3	NRC staff should provide information that describes safety culture problems as contributing factors to violations.	5/25/10	NRC action	Closed 9/29/10
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	Accepted	Open
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	Accepted	Open
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	NRC action	Open
7	The ACMUI fully supports Dr. Darrell Fisher as Patients' Rights Advocate. The Committee expressed their appreciation and honor to serve with him.	5/25/10	No NRC action	Closed
8	NRC staff should provide optimal staff and support to facilitate the licensing process for new domestic producers of the medical isotope, molybdenum 99.	5/25/10	Acknowledged	Closed