

2007 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
1	NRC staff should issue an (IN), which describes errors previously made and provides examples of best practices with regards units of AKS vs. apparent activity (mCi) for brachytherapy sources. The IN should be done in collaboration with the American Association of Physicists in Medicine (AAPM) and coordinated with Agreement States.	6/12/07	Accepted	Closed 9/9/09
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	Closed 3/7/18
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	Closed 3/7/18
4	NRC staff should reduce the 200-hour radiation safety training requirement to 120 hours for individuals seeking authorization under the alternate pathway in 10 CFR 35.390.	6/12/07	Not accepted	Closed
5	NRC staff should not change the current definition for a RSO.	6/13/07	Accepted	Closed
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	Closed 3/7/18

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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	Closed 3/7/18
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	Closed 3/7/18
9	ACMUI tabled the following issue until the next full ACMUI meeting: 35.57(a), 35.75, 35.491(b)(2), 35.400, 35.500, and 35.600.	6/13/07	Moved to Oct Agenda	Closed
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) Closed 3/7/18 b) Closed

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11	NRC staff should include the three-case work experience requirement for individuals seeking authorization for Y-90 microsphere use; however, the three cases do not have to be with the particular type of microsphere for which the individual is seeking authorization. Furthermore, ACMUI recommends the training and experience does not have to be performed under the supervision of an AU, and NRC staff should replace the proposed supervision paragraph with the existing language from 10 CFR 35.690(c).	6/13/07	Partially accepted, Revised guidance published 09/07	Closed
12	NRC staff should delete the attestation requirement for Y-90 microspheres users and incorporate a requirement in the second paragraph of the guidance for individuals seeking authorization to provide and retain documentation of the completion of training.	6/13/07	Accepted, Revised guidance published 09/07	Closed
13	NRC staff should incorporate the proposed wording for the team approach section of the Y-90 microspheres guidance with one exception: ACMUI recommends the word “oncology” be replaced by “cancer management.”	6/13/07	Accepted, Revised guidance published 09/07	Closed
14	For 10 CFR 35.1000 guidance documents, NRC staff should incorporate the proposed wording that notification under 10 CFR 35.14 does not apply for specific medical use licensees.	6/13/07	Moved to 10/07 agenda for clarification	Closed
15	ACMUI tabled the absorbed dose vs. activity issue for Y-90 microspheres until the next full ACMUI meeting.	6/13/07	Moved to 10/07 agenda	Closed

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16	NRC staff should revise the current guidance to conclude that the surgical removal of the sentinel lymph node is an independent procedure and should not be regulated by NRC.	6/13/07	Accepted	Closed 1/9/09
17	NRC staff committed to consult legal counsel to determine the feasibility of discussing PRM 35-20 (Ritenour/AAPM petition) with ACMUI members in a closed executive session.	6/13/07	Completed, added to 10/07 agenda	Closed
18	NRC staff should arrange a briefing for ACMUI members regarding the Increased Controls Orders to be issued later this year for fingerprinting.	6/13/07	Completed, 8/15/07 meeting	Closed
19	NRC staff should engage ACMUI in a discussion regarding the review of operational events and data and work towards a goal of minimizing therapeutic medical events, if directed by the Commission to do so.	6/13/07	Not directed by Commission; NRC may request in future	N/A
20	NRC staff should provide detailed background information for the current and future presentations on the subject of potential changes to 10 CFR Part 35.	6/13/07	Accepted, on going	N/A
21	NRC staff should email the ACMUI members a copy of the memo summarizing action items and motions made during the meeting.	6/13/07	Accepted, ongoing	N/A
22	ACMUI supports grandfathering for individuals who had previously been determined to be trustworthy and reliable and granted unescorted access.	8/15/07	Not accepted, Orders mailed 10/07	Closed

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23	ACMUI agrees to assist the NRC, if requested, to determine those levels and types of material that could be of such significance to public health and safety to warrant fingerprinting and background checks.	8/15/07	Not requested, Orders mailed 10/07	Closed
24	NRC staff should revise the current regulations to include Canadian trained individuals who have passed the ABNM certification exam.	8/16/07	Accepted	Closed on 3/7/18
25	NRC staff should maintain Compatibility B for training and experience requirements to ensure that authorized individuals may cross state borders and practice throughout the U.S.	8/16/07	Accepted	Closed
26	NRC staff should accept a preceptor statement from another AU for a non-board certified individual if the AU who supervised the training and work experience is not available as a preceptor.	9/20/07	Accepted, current NRC practice	Closed
27	NRC staff should add 'increased complexity vs. additional benefit' as an agenda item for the October ACMUI meeting, so that ACMUI may continue the discussion on this topic.	9/20/07	Moved to October 2007 agenda	Closed
28	The AU should be required to place a signature on orders for radioactive material before the supplier can legally ship the material to an institution.	10/22/07	Motion did not pass	Closed
29	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>
30	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	Closed 3/7/18

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31	NRC staff should not require experienced RSOs to obtain written attestation to become authorized or have responsibility for new uses.	10/22/07	Accepted	Closed 3/7/18
32	NRC staff should <u>not</u> revise 10 CFR 35.75 to read “5 mSv/ <u>year</u> (0.5 rem/ <u>year</u>).”	10/23/07	Not accepted	Closed
33	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>
34	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>
35	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	Closed 3/7/18
36	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	Closed 3/7/18