

2021 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
1	The ACMUI tentatively scheduled its fall 2021 meeting for October 4-5, 2021. The meeting will be held virtually. The next ACUI Commission meeting is scheduled for October 5, 10am-12pm EDT.	3/16/2021	ACMUI Action	Closed
2	The ACMUI formed a subcommittee to review and evaluate the training and experience requirements for eluting, measuring, testing, and processing the eluate from radionuclide generator systems; to evaluate and determine the appropriateness of the requirements and how best to obtain the training and experience; and to evaluate whether and how additional training should be obtained as necessary to supervise the use of any radionuclide generator system.	5/27/2021	ACMUI Action	Closed
3	The ACMUI formed a subcommittee to outline the knowledge and specific or specialized practice or policy requirements needed for the safe use and handling of emerging radiopharmaceuticals in theranostics.	5/27/2021	ACMUI Action	Closed
4	The ACMUI endorsed the Abnormal Occurrence Subcommittee report, to include a recommendation to fully support the proposed changes to the medical AO criteria as outlined in Enclosure 1 of the Subcommittee's report.	7/1/2021	NRC Action	Open
5	The ACMUI endorsed the Abnormal Occurrence Subcommittee report, to include a recommendation to prepare some type of communication for distribution to all NRC and Agreement State medical licensees to inform them of best practices in preparing a medical event report so that complete and accurate information is provided in describing the event, root cause analysis on why the event occurred, and the medical effect on the individual(s).	9/16/2021	NRC Action	Open

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6	The ACMUI unanimously endorsed the Subcommittee on Extravasation's report, as amended, to include a recommendation to support the NRC's staff Option 4.	10/4/2021	NRC Action	Open
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7	The ACMUI endorsed the Subcommittee on Radionuclide Generator Knowledge and Practice Requirements' report, to include a recommendation to propose a revision to the current rule language in 10 CFR 35.290(c)(1)(ii)(G) to read as follows: (G) "Participating in educational sessions to gain knowledge and provide supervision of –(1) radionuclide generator systems and their operation; (2) the measurement of radionuclidic impurities and acceptable limits; and (3) the use of reagent kits with radionuclide eluate to prepare radioactive drugs."	10/4/2021	NRC Action	Open
8	The ACMUI formed a subcommittee to provide an in-depth re-evaluation of Y-90 related medical events, including a focus on the technical components and with vendor/industry input propose guidance and methods to decrease the number of Y-90 related medical events.	10/4/2021	ACMUI Action	Closed
9	The ACMUI formed a subcommittee to review the Liberty Vision technology and review the licensing guidance and comment on the NRC staff's draft LV Liberty Vision Y-90 Eye Brachytherapy Source Licensing Guidance	10/4/2021	ACMUI Action	Open
10	The ACMUI tentatively scheduled its spring 2022 meeting for April 4-5, 2022. The alternate date is March 21-22, 2022. The meeting is expected to be held in person.	10/4/2021	ACMUI Action	Open
11	The ACMUI unanimously endorsed the Alpha Dart Subcommittee report.	12/15/2021	NRC Action	Open

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12	The ACMUI unanimously endorsed the Subcommittee on Regulatory Guide 8.39, Revision 2's report on the draft licensing guidance for the superficial manual brachytherapy CivaDerm device, recommending that CivaDerm should be licensed under 10 CFR 35.400 and that the NRC staff develop a shorter guidance document that focuses on the consequences of loose or dislodged sources.	12/15/2021	NRC Action	Open
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13	The ACMUI unanimously endorsed the Subcommittee on Regulatory Guide 8.39, Revision 2's report on the NRC staff's proposed revision 2 to RG 8.39, "Release of Patients Administered Radioactive Materials." The Subcommittee made six recommendations and provided specific comments related to the patient instructions, occupancy factors, hold times, and calculation methodologies.	12/15/2021	NRC Action	Open