2017 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
1	The Committee requested that the recommendations and actions pertaining to the Part 35 rulemaking be reviewed during the fall 2017 ACMUI neeting and that additional time be provided to review each item.	4/26/2017	NRC Action	*Pending*
8	The Patient Intervention Subcommittee will amend its Subcommittee Report and will report at the ACMUI fall 2017 meeting or by teleconference to discuss their amended report.	4/27/2017	ACMUI Action	Closed 3/7/18
12	The NRC staff will engage in discussions with the OAS to find a way to centralize event reporting from the Agreement States.	9/11/2017	NRC Action	Open
13	The ACMUI recommended that the NRC establish a program allowing a medical use licensee to evaluate MEs as described in 10 CFR 35.3045, in NRC 10 CFR 35.1000 licensing guidance, and in 10 CFR 35.3047 with an approved patient safety program.	9/11/2017	NRC Action	Open

14	The ACMUI recommended that NRC licensees with an NRC-approved patient safety program will continue to report medical events as required with the following conditions: (1) The NRC will not include this event notification in the Event Notification Report posted on its website. If this is not possible, the ME notification posted on the website will leave the licensee information and location anonymous. (2) The NRC will not conduct a reactive inspection of the ME unless the event results or will result in death, unintended permanent harm, or unintended significant temporary harm for which medical intervention was or will be required to alleviate the harm or reduce radiation effects. (3) The medical use licensee will write a report available for the next NRC inspection describing the event cause and corrective action taken. (4) NRC will develop, with ACMUI advice, new temporary inspection procedures for NRC review of licensee patient safety event reports, and will evaluate, with ACMUI advice, need to change enforcement manual procedures regarding MEs to support a test of this program.	9/11/2017	NRC Action	Open

15	The ACMUI recommended that NRC should test out this program with two large medical centers, two community hospitals, two rural hospitals, and two patient clinics for a year, evaluating the ME reports with the ACMUI. During this test period, the NRC, with advice from the ACMUI, should do the following: (1) Develop the minimum criteria for patient safety program reviews; (2) Assess how this change in ME reporting impacts the NRC's ability to protect patient health and to minimize danger to the patient's life; and (3) Evaluate the different types of patient safety programs in how lessons learned from their patient safety incident reviews are shared with the medical community.	9/11/2017	NRC Action	Open
16	The ACMUI recommended that after completion of the test year, the NRC should consider opening the program to all NRC medical use licensees who request approval of their patient safety program, and to Agreement States who request to implement the program with their medical licensees.	9/11/2017	NRC Action	Open
17	The ACMUI recommended that the NRC redefine its perspective of patient safety to be different from occupational safety and from public safety.	9/11/2017	NRC Action	Open
18	The ACMUI recommended that NRC partner with the Department of Health and Human Services (HHS), specially the Agency for Healthcare and Research and Quality (AHRQ) , and ACMUI to develop a national database taxonomy specific for reporting patient events involving medical use of byproduct material.	9/11/2017	NRC Action	Open

19	The ACMUI recommended that the NRC Update its Medical Use Policy Statement and 10 CFR 35 event reporting regulations for patient safety programs to verify the active involvement of the licensee's patient safety program review of medical errors and reporting of reviews to the national patient safety database.	9/11/2017	NRC Action	Open
20	The ACMUI endorsed the Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture Draft Report, as amended to support the concept of the pilot program with the total number of sites and duration to be determined at a later date and to include the Patient Intervention Subcommittee recommendations as an addendum .	9/11/2017	ACMUI Action	Open
21	The ACMUI will hold a public teleconference in the near future to discuss the amended Nursing Mothers Guidelines Subcommittee Report. Amendments will include, but are not limited to: (1) a suggested time frame for providing written and oral instructions to patients who will stop breastfeeding altogether and (2) consideration to revise the radionuclides to be non-pharmaceutical specific.	9/11/17	ACMUI Action	Closed 2/15/18
22	The ACMUI commented (1) that the literature review was thorough and the model calculations sound; and (2) the current dose-based approach to assessing patient releasability validated as more protective of public safety than the activity-based approach.	9/11/17	ACMUI Action	Closed 3/7/18

23	The ACMUI recommended that the current 5-mSv (500-mrem) and 1-mSv (100-mrem) projected dose limits for family members and the general public, respectively, should remain a per-event limit and are appropriate for all potentially exposed cohorts, including pregnant women and children, and all radionuclide administrations.	9/11/17	NRC Action	Closed 3/7/18
24	The ACMUI recommended that the 1-mSv (100-mrem) dose limit for requiring patient safety instructions should remain in place.	9/11/17	NRC Action	Closed 3/7/18
25	The ACMUI commented that (1) the assumption in regulatory guidance that the internal dose contribution is negligible has been validated; (2) other assumptions and methods in regulatory guidance are excessively conservative NCRP Report No 155; and (3) a patient staying at a hotel following radionuclide therapy is not a widespread practice and is unlikely to result in doses to workers and others > 1 mSv (100 mrem).	9/11/17	ACMUI Action	Closed 3/7/18
26	The ACMUI recommended that instructions must be provided to the patient well in advance of a planned therapy (ie not on the day of administration), without compromising patient care. Specification of a regulatory time interval for pre-therapy instructions is not recommended --> NCRP Report No 155.	9/11/17	NRC Action	Closed 3/7/18

27	The NRC recommended that the NRC should consider updating Appendix U (NUREG 1556) to reference Regulatory Guide 8.39 rather than eliminating 8.39 or maintaining two separate guidance documents.	9/11/17	NRC Action	Closed 3/7/18
28	The ACMUI endorsed the Patient Release SECY Paper Subcommittee Report.	9/11/17	ACMUI Action	Closed 3/7/18
29	The ACMUI will hold a public teleconference in the near future to discuss the amended Physical Presence Requirements for the Leksell Gamma Knife Icon Subcommittee Report. Amendments will include (1) the distinction between "an" or "the" AU or AMP;" (2) AU presence for re-initiation of procedure following interruption; (3) possible incorporation of changes to the physical presence requirements for the Leksell Gamma Knife Perfexion; and (4) whether the physical presence requirements will be limited to the frame-based or frameless-based option for the Leksell Gamma Knife Icon.	9/12/17	ACMUI Action	Closed 2/15/18
30	The Committee tentatively scheduled the spring 2018 ACMUI meeting for March 1-2, 2018. The back-up dates are March 14-15, 2018. The final meeting date is subject to Commission availability.	9/12/17	ACMUI Action	Closed