

MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
September 20–21, 2018

One White Flint North Building (Commission Hearing Room), Rockville, Maryland

NOTE: Sessions of the meeting may be closed pursuant to 5 U.S.C. 552(b) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACMUI; information the release of which would constitute a clearly unwarranted invasion of personal privacy; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and disclosure of information which would risk circumvention of an agency regulation or statute.

Thursday, September 20, 2018
CLOSED SESSION

7:30 – 8:30	1. Badging and Enrollment	PERSEC, NRC
8:30 – 9:00	2. INFOSEC Training	R. Norman, NRC
9:00 – 9:30	3. Allegations Training	D. Willis, NRC
10:00 – 10:30	4. ETHICS Training	J. Suttenger & J. Ezell, NRC

10:30 – 11:00 **BREAK**

OPEN SESSION

11:00 – 11:15	5. Opening Remarks Mr. Bollock will formally open the meeting and Ms. Attack will provide opening comments.	D. Bollock & S. Attack, NRC
11:15 – 11:30	6. Old Business Ms. Dimmick will review past ACMUI recommendations and provide NRC responses.	L. Dimmick, NRC
11:30 – 11:45	7. Open Forum The ACMUI will identify medical topics of interest for further discussion.	ACMUI

11:45 – 12:45 **LUNCH**

12:45 – 1:30	8. Medical Events Subcommittee Report Dr. Ennis will present the subcommittee's analysis of medical events for fiscal year 2017.	R. Ennis, ACMUI
1:30 – 2:00	9. Non-Medical Events Mr. Sheetz will discuss non-medical events reported by medical use facilities and commercial pharmacies for fiscal year 2017.	M. Sheetz, ACMUI
2:00 – 2:30	10. ABS Medical Event Case Study Program Mr. Ouhib will discuss the American Brachytherapy Society's effort to reach out to the brachytherapy community for creative corrective actions regarding events that have taken place.	Z. Ouhib, ACMUI

2:30 – 2:45 **BREAK**

2:45 – 3:05	11. T&E for All Modalities Subcommittee Update Dr. Metter will provide an update on the actions of the training and experience for all modalities subcommittee and the planned path forward.	D. Metter, ACMUI
3:05 – 3:35	12. T&E Stakeholder Outreach Plan Ms. Ayoade will present the staff's outreach plan for the continued evaluation of training and experience.	M. Ayoade, NRC
3:35 – 3:55	13. ACMUI-SNMMI Session at the 2018 SNMMI Annual Meeting Dr. Palestro will provide an overview of the topics discussed by ACMUI at the 2018 Society of Nuclear Medicine and Molecular Imaging meeting in Philadelphia, PA.	C. Palestro, ACMUI
3:55 – 4:15	14. Nursing Mother Guidelines Subcommittee Report Dr. Metter will discuss the subcommittee's final report on the nursing mother guidelines for exposure from diagnostic and therapeutic radiopharmaceuticals.	D. Metter, ACMUI
4:15 – 5:00	15. ACMUI Comments on the Draft Revision of the Leksell Gamma Knife Perfexion and Leksell Gamma Knife Icon Licensing Guidance Dr. Suh will discuss the subcommittee's comments on the draft revision of the Leksell Gamma Knife Perfexion and Leksell Gamma Knife Icon licensing guidance.	J. Suh, ACMUI

Friday, September 21, 2018
OPEN SESSION

8:30 – 8:45	16. Special Presentation to Dr. Suh Mr. Dapas will make a special presentation to Dr. Suh.	M. Dapas, NRC
8:45 – 9:00	17. Dr. Suh's Thoughts on Leaving ACMUI Dr. Suh will share his thoughts on leaving the ACMUI.	J. Suh, ACMUI
9:00 – 9:15	18. Special Presentation to Dr. Alderson Mr. Dapas will make a presentation to Dr. Alderson.	M. Dapas, NRC
9:15 – 9:30	19. Dr. Alderson's Thoughts on Leaving ACMUI Dr. Alderson will share his thoughts on leaving the ACMUI.	P. Alderson, ACMUI
9:30 – 9:50	20. ACMUI Comments on the Draft Ge-68/Ga-68 Generator Licensing Guidance Mr. Green will discuss the subcommittee's comments on the draft Germanium-68/Gallium-68 Generator Licensing Guidance.	R. Green, ACMUI
9:50 – 10:15	21. Medical Team Highlights Ms. Dimmick will recap the work of the Medical Radiation Safety Team for fiscal year 2018.	L. Dimmick, NRC

10:15 – 10:45	BREAK
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10:45 – 11:30	22. Y-90 Microspheres Brachytherapy Licensing Guidance Dr. Tapp will discuss the current status of the yttrium-90 working group's revised guidance and planned actions.	K. Tapp, NRC
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11:30 – 12:00	23. Compounding of Sterile and Non-Sterile Radiopharmaceuticals Mr. Green will discuss the establishment of an Expert Panel by USP to develop USP Standards of sterile and non-sterile radiopharmaceutical preparation.	R. Green, ACMUI
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12:00 – 1:00	LUNCH
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1:00 – 2:00	24. ACMUI, Subcommittees, NRC staff, NRC management: How the Team Works Under FACA Mr. Chazell and Mr. Bollock will discuss the roles and responsibilities of each under the Federal Advisory Committee Act (FACA).	R. Chazell & D. Bollock, NRC
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2:00 – 2:45	25. ACMUI Subcommittees, Subcommittee Membership, and the ACMUI Chair Dr. Palestro will discuss the possible need for ACMUI bylaw changes and the need to update subcommittee membership, form new subcommittees and sunset other subcommittees.	C. Palestro, ACMUI
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2:45 – 3:00	26. Licensing Th-227 Chloride Ms. Dimmick will discuss the current status of licensing thorium-227 chloride for medical use.	L. Dimmick, NRC
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3:00 – 3:15	27. Open Forum The ACMUI will discuss medical topics of interest previously identified.	ACMUI
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3:15 – 3:30	28. Administrative Closing Ms. Dimmick will provide a meeting summary and propose dates for the spring 2019 meeting.	L. Dimmick, NRC
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3:30	ADJOURN
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