

MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
September 10–11, 2019

Two White Flint North Building (T-2D30), 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.

Tuesday, September 10, 2019
CLOSED SESSION

7:30 – 8:30

1. Badging and Enrollment

ACMUI

OPEN SESSION

2. Opening Remarks

Mr. Einberg will formally open the meeting and Ms. Kock will provide opening remarks.

C. Einberg, NRC
A. Kock, NRC

3. Old Business

Ms. Jamerson will review past ACMUI recommendations and provide NRC responses.

K. Jamerson, NRC

8:30 – 10:30

4. Open Forum

The ACMUI will identify medical topics of interest for further discussion.

ACMUI

5. Training and Experience Evaluation

Ms. Lopas and Ms. Ayoade will provide an update on the staff's evaluation of the training and experience requirements for radiopharmaceuticals requiring a written directive.

M. Ayoade, NRC
S. Lopas, NRC

6. Medical Events Subcommittee Report

Dr. Ennis will provide an analysis of FY18 medical events.

R. Ennis, ACMUI

10:30 – 10:45

BREAK

7. Appropriateness of Medical Event Reporting Subcommittee Report

R. Ennis, ACMUI

10:45 – 12:15

Dr. Ennis will discuss the subcommittee's recommendations on the appropriateness of the required medical event reporting in accordance with 10 CFR 35.3045.

8. Evaluation of Infiltrations Subcommittee Report

M. Martin, ACMUI

Ms. Martin will discuss the subcommittee's recommendations on the evaluation of the NRC's 1980 infiltration decision.

12:15 – 1:30

LUNCH

1:30 – 2:45	9. Special Presentation to Dr. Palestro Chairman Svinicki will make a special presentation to Dr. Palestro.	K. Svinicki, NRC
	10. Dr. Palestro’s Thoughts on Leaving the ACMUI Dr. Palestro will share his thoughts on leaving the ACMUI, after serving eight years, two of which he served as ACMUI Chairman.	C. Palestro, ACMUI
	11. Xcision GammaPod Licensing Guidance Subcommittee Report Dr. Wolkov will discuss the subcommittee’s recommendations on the NRC’s draft Xcision® GammaPod Licensing Guidance.	H. Wolkov, ACMUI
2:45 – 3:00		
BREAK		
Tuesday, September 10, 2019		
CLOSED SESSION		
3:00 – 5:00	12. INFOSEC Training	R. Norman, NRC
	13. Ethics Training	C. Safford, NRC
	14. Allegations Training	S. Hawkins, NRC
Wednesday, September 11, 2019		
OPEN SESSION		
8:30 – 10:30	15. Reducing Radioactive Materials Ms. Taalbi will provide an overview of the NNSA’s initiative to reduce radioactive materials using alternative technologies.	M. Taalbi, NNSA
	16. ACMUI’s Institutional Memory Subcommittee Report Dr. Schleipman will discuss the subcommittee’s recommendations for improving the ACMUI’s institutional memory.	A. Schleipman, ACMUI
	17. Open Forum The ACMUI will discuss medical topics of interest previously identified.	ACMUI
	18. ACMUI External Communications Dr. Palestro will discuss the 2019 Society of Nuclear Medicine and Molecular Imaging Annual Meeting.	C. Palestro, ACMUI
10:30 – 10:45		
BREAK		
10:45 – 11:15	19. NRC Regulatory Process and Other Tools NRC staff will provide an overview of NRC’s regulatory process, to include the lifecycle of ACMUI recommendations and open items from initiation to disposition.	I. Irvin, NRC
	20. Status of Emerging Technologies Licensed under 10 CFR 35.1000 Mr. Sheetz will provide a presentation on the status of emerging technologies licensed under 10 CFR 35.1000.	M. Sheetz, ACMUI

21. U.S. Pharmacopeia (USP) General Chapter <825>

R. Green, ACMUI

Mr. Green will provide a presentation on the new USP General Chapter <825> for Radiopharmaceuticals.

11:45 – 1:00

22. ACMUI Membership Composition and Balance

L. Dimmick, NRC

Ms. Dimmick will provide a discussion of the ACMUI membership and balance.

23. Administrative Closing

K. Jamerson, NRC

Ms. Jamerson will provide a meeting summary and propose dates for the spring 2020 meeting.

1:00

ADJOURN