

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

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

R. Ennis, ACMUI

10:45 – 12:15

8. Evaluation of Infiltrations Subcommittee Report

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

M. Martin, ACMUI

12:15 – 1:30

LUNCH

9. Special Presentation to Dr. Palestro

Chairman Svinicki will make a special presentation to Dr. Palestro.

K. Svinicki, NRC

1:30 – 2:45

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

13. Ethics Training

14. Allegations Training

R. Norman, NRC

C. Safford, NRC

S. Hawkins, NRC

Wednesday, September 11, 2019

OPEN SESSION

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

8:30 – 10:30

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

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

10:45 – 11:15

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>

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

R. Green, ACMUI

11:45 – 1:00

22. ACMUI Membership Composition and Balance

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

L. Dimmick, NRC

23. Administrative Closing

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

K. Jamerson, NRC

1:00

ADJOURN