

**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**

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| 7:30 – 10:30 | <ul style="list-style-type: none"> <li>• <b>Badging and Enrollment</b></li> <li>• <b>INFOSEC Training</b></li> <li>• <b>Ethics Training</b></li> <li>• <b>Allegations Training</b></li> </ul> | <p><b>PERSEC, NRC</b><br/><b>R. Norman, NRC</b><br/><b>J. Suttenger &amp; J. Ezell, NRC</b><br/><b>D. Willis, NRC</b></p> |
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10:30 – 11:00 **BREAK**

**OPEN SESSION**

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|               | <ul style="list-style-type: none"> <li>• <b>Opening Remarks</b><br/>Mr. Bollock will formally open the meeting and Ms. Atack will provide opening comments.</li> </ul>  | <p><b>D. Bollock &amp; S. Atack, NRC</b></p>      |
| 11:00 – 11:45 | <ul style="list-style-type: none"> <li>• <b>Old Business</b><br/>Ms. Dimmick will review past ACMUI recommendations and provide NRC responses.</li> <li>• <b>Open Forum</b><br/>The ACMUI will identify medical topics of interest for further discussion.</li> </ul> | <p><b>L. Dimmick, NRC</b></p> <p><b>ACMUI</b></p> |

11:45 – 12:45 **LUNCH**

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|              | <ul style="list-style-type: none"> <li>• <b>Medical Events Subcommittee Report</b><br/>Dr. Ennis will present the subcommittee’s analysis of medical events for fiscal year 2017.</li> </ul>   | <p><b>R. Ennis, ACMUI</b></p>                                |
| 12:45 – 2:30 | <ul style="list-style-type: none"> <li>• <b>Non-Medical Events</b><br/>Mr. Sheetz will did non-medical events reported by medical use facilities and commercial pharmacies.</li> <li>• <b>ABS Medical Event Case Study Program</b><br/>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.</li> </ul> | <p><b>M. Sheetz, ACMUI</b></p> <p><b>Z. Ouhib, ACMUI</b></p> |

2:30 – 2:45 **BREAK**

- 2:45 – 5:00

  - **T&E for All Modalities Subcommittee Update** **D. Metter, ACMUI**  
 Dr. Metter will provide an update on the actions of the training and experience for all modalities subcommittee and the planned path forward.
  - **T&E Stakeholder Outreach Plan** **M. Ayoade, NRC**  
 Ms. Ayoade will present the staff's outreach plan for the continued evaluation of training and experience.
  - **ACMUI-SNMMI Session at the 2018 SNMMI Annual Meeting** **C. Palestro, ACMUI**  
 Dr. Palestro will provide an overview of the topics discussed by ACMUI at the 2018 SNMMI meeting in Philadelphia, PA.
  - **Nursing Mother Guidelines Subcommittee Report** **D. Metter, ACMUI**  
 Dr. Metter will discuss the subcommittee's final report on the nursing mother guidelines for exposure from diagnostic and therapeutic radiopharmaceuticals.
  - **ACMUI Comments on the Draft Revision of the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance** **J. Suh, ACMUI**  
 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.

**Friday, September 21, 2018**  
**OPEN SESSION**

- 8:30 – 10:15

  - **Special Presentation to Dr. Suh** **M. Dapas, NRC**  
 Mr. Dapas will make a special presentation to Dr. Suh.
  - **Dr. Suh's Thoughts on Leaving ACMUI** **J. Suh, ACMUI**  
 Dr. Suh will share his thoughts on leaving the ACMUI.
  - **Special Presentation to Dr. Alderson** **M. Dapas, NRC**  
 Mr. Dapas will make a presentation to Dr. Alderson.
  - **Dr. Alderson's Thoughts on Leaving ACMUI** **P. Alderson, ACMUI**  
 Dr. Alderson will share his thoughts on leaving the ACMUI.
  - **Y-90 Microspheres Brachytherapy Licensing Guidance** **K. Tapp, NRC**  
 Dr. Tapp will discuss the current status of the yttrium-90 working group's revised guidance and planned actions.

10:15 – 10:45 **BREAK**

- 10:45 – 11:15

  - **Compounding of Sterile and Non-Sterile Radiopharmaceuticals** **R. Green, ACMUI**  
 Mr. Green will discuss the establishment of an Expert Panel by USP to develop USP Standards of sterile and non-sterile radiopharmaceutical preparation.

- 11:15 – 12:00

• **Medical Team Highlights** **L. Dimmick, NRC**  
 Ms. Dimmick will recap the work of the Medical Radiation Safety Team for fiscal year 2018.

• **Open Forum** **ACMUI**  
 The ACMUI will discuss medical topics of interest previous identified.

12:00 – 1:00 **LUNCH**

- 1:00 – 3:00

• **ACMUI, Subcommittees, NRC staff, NRC management: How the Team Works Under FACA** **R. Chazell & D. Bollock, NRC**  
 Mr. Chazell and Mr. Bollock will discuss the roles and responsibilities of each under the Federal Advisory Committee Act (FACA).

• **ACMUI Subcommittees, Subcommittee Membership, and the ACMUI Chair** **C. Palestro, ACMUI**  
 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.

• **Administrative Closing** **L. Dimmick, NRC**  
 Ms. Dimmick will provide a meeting summary and propose dates for the spring 2019 meeting.

3:00 **ADJOURN**