

**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	<b>1. Badging and Enrollment</b>	<b>PERSEC, NRC</b>
8:30 – 9:00	<b>2. INFOSEC Training</b>	<b>R. Norman, NRC</b>
9:00 – 9:30	<b>3. Allegations Training</b>	<b>D. Willis, NRC</b>
10:00 – 10:30	<b>4. ETHICS Training</b>	<b>J. Suttenger &amp; J. Ezell, NRC</b>

10:30 – 11:00 **BREAK**

**OPEN SESSION**

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

11:45 – 12:45 **LUNCH**

12:45 – 1:30	<b>8. Medical Events Subcommittee Report</b> Dr. Ennis will present the subcommittee's analysis of medical events for fiscal year 2017.	<b>R. Ennis, ACMUI</b>
1:30 – 2:00	<b>9. Non-Medical Events</b> Mr. Sheetz will discuss non-medical events reported by medical use facilities and commercial pharmacies for fiscal year 2017.	<b>M. Sheetz, ACMUI</b>
2:00 – 2:30	<b>10. ABS Medical Event Case Study Program</b> 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.	<b>Z. Ouhib, ACMUI</b>

2:30 – 2:45 **BREAK**

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

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

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

10:15 – 10:45

**BREAK**

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| 10:45 – 11:30 | <b>22. Y-90 Microspheres Brachytherapy Licensing Guidance</b><br>Dr. Tapp will discuss the current status of the yttrium-90 working group's revised guidance and planned actions.  | K. Tapp, NRC                 |
| 11:30 – 12:00 | <b>23. Compounding of Sterile and Non-Sterile Radiopharmaceuticals</b><br>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              |
| 12:00 – 1:00  | <b>LUNCH</b>   |                              |
| 1:00 – 2:00   | <b>24. ACMUI, Subcommittees, NRC staff, NRC management: How the Team Works Under FACA</b><br>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 |
| 2:00 – 2:45   | <b>25. ACMUI Subcommittees, Subcommittee Membership, and the ACMUI Chair</b><br>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           |
| 2:45 – 3:00   | <b>26. Licensing Th-227 Chloride</b><br>Ms. Dimmick will discuss the current status of licensing thorium-227 chloride for medical use.   | L. Dimmick, NRC              |
| 3:00 – 3:15   | <b>27. Open Forum</b><br>The ACMUI will discuss medical topics of interest previous identified.  | ACMUI                        |
| 3:15 – 3:30   | <b>28. Administrative Closing</b><br>Ms. Dimmick will provide a meeting summary and propose dates for the spring 2019 meeting.   | L. Dimmick, NRC              |

3:30	<b>ADJOURN</b>
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