

# MEETING AGENDA

## ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

**October 6-7, 2016**  
**Two White Flint North Building (T2-B3), 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.

<b>Thursday, October 06, 2016</b>		
<b>CLOSED SESSION</b>		
<b>7:00 – 8:00</b>	<b>1. Badging and Enrollment</b>	<b>ACMUI</b>
<b>OPEN SESSION</b>		
	<b>2. Opening Remarks</b>	<b>D. Bollock, NRC</b>
	Mr. Bollock will formally open the meeting and Mr. Collins will provide opening comments.	<b>D. Collins, NRC</b>
	<b>3. Old Business</b>	<b>M. Smethers, NRC</b>
	Ms. Smethers will review past ACMUI recommendations and provide NRC responses.	
<b>8:00 – 10:15</b>	<b>4. Open Forum</b>	<b>ACMUI</b>
	The ACMUI will identify medical topics of interest for further discussion.	
	<b>5. Event Reporting Mechanisms</b>	<b>ASTRO/AAPM, CARS, CRCPD, IAEA</b>
	Multiple organizations will discuss and share information related to their event reporting databases.	
<b>10:15 – 10:30</b>	<b>BREAK</b>	
<b>10:30 – 11:30</b>	<b>6. Medical Events Subcommittee Report</b>	<b>R. Ennis, ACMUI</b>
	Dr. Ennis will present the subcommittee's analysis of medical events for fiscal year 2015.	
<b>11:30 – 1:00</b>	<b>LUNCH</b>	
	<b>7. Medical Event Reporting for All Modalities Excluding Permanent Implant Brachytherapy</b>	<b>J. Suh, ACMUI</b>
	Dr. Suh will discuss the subcommittee's recommendations for the reporting of medical events.	
<b>1:00 – 2:30</b>	<b>8. 10 CFR Part 35 Rulemaking Update</b>	<b>T. Taylor, NRC</b>
	Ms. Taylor will provide an update on the 10 CFR Part 35 rulemaking effort.	
	<b>9. NRC Comments on 'Patient Intervention'</b>	<b>M. Fuller, NRC</b>
	Mr. Fuller will discuss staff's comments in response to the ACMUI's Patient Intervention Subcommittee Report.	
<b>2:30 – 3:00</b>	<b>BREAK</b>	
<b>CLOSED SESSION</b>		
<b>3:00 – 5:00</b>	<b>10. Ethics Training</b>	<b>M. Clark, NRC</b>
	<b>11. INFOSEC Training</b>	<b>R. Norman, NRC</b>
	<b>12. Allegations Training</b>	<b>S. Hawkins, NRC</b>

	<b>13. Yttrium-90 Microspheres Brachytherapy Licensing Guidance</b> Dr. Tapp will provide an overview of the revisions to the Y-90 Microspheres Brachytherapy Licensing Guidance. Dr. Metter will provide the subcommittee's comments on the proposed revisions.	<b>K. Tapp, NRC D. Metter, ACMUI</b>
8:00 – 10:15	<b>14. NRC's Abnormal Occurrence Criteria Policy Statement Update</b> Dr. Oxenberg will provide an update on the proposed revisions to the Abnormal Occurrence Criteria Policy Statement.	<b>T. Oxenberg, NRC</b>
	<b>15. Training and Experience for All Modalities</b> Dr. Palestro will discuss the subcommittee's comments on the T&E requirements for authorized individuals in 10 CFR Part 35.	<b>C. Palestro, ACMUI</b>
10:15 – 10:30	<b>BREAK</b>	
10:30 – 11:30	<b>16. Spectrum Pharmaceuticals Proposal for Training and Experience Requirements</b> Representatives from Spectrum Pharmaceuticals, Inc. will discuss their proposed revisions to the T&E requirements for alpha and beta emitters.	<b>Spectrum Pharmaceuticals, Inc.</b>
11:30 – 1:00	<b>LUNCH</b>	
	<b>17. Worldwide Supply of Molybdenum-99</b> Mr. Green will provide an update of the world's supply of moly-99.	<b>R. Green, ACMUI</b>
1:00 – 2:30	<b>18. NorthStar Generator Licensing Guidance</b> Dr. Howe will provide an overview of the 10 CFR 35.1000 licensing guidance drafted by an NRC/OAS working group. Dr. Dilsizian will provide the subcommittee's comments on the proposed guidance.	<b>DB. Howe, NRC V. Dilsizian, ACMUI</b>
2:30 – 3:00	<b>BREAK</b>	
	<b>19. Germanium-68/Gallium-68 Medical Use Generator Licensing Guidance</b> Dr. Tapp will provide an overview of the 10 CFR 35.1000 licensing guidance drafted by an NRC/OAS working group.	<b>K. Tapp, NRC</b>
3:00 – 4:00	<b>20. Germanium-68/Gallium-68 Medical Use Generator Decommissioning Funding Plan Update</b> Dr. Daibes will provide an update on staff's efforts to address the decommissioning funding issues related to the germanium/gallium-68 medical use generator.	<b>S. Daibes, NRC</b>
	<b>21. Enhancing Communications with the Medical Community</b> Dr. Alderson will provide an update on the ACMUI's efforts to improve the ACMUI and NRC's communications with various medical professional societies.	<b>P. Alderson, ACMUI</b>

**22. Administrative Closing**

**M. Smethers, NRC**

Ms. Smethers will provide a meeting summary and propose dates for the spring 2017 meeting.

4:00

**ADJOURN**