

**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.

**Thursday, October 06, 2016  
CLOSED SESSION**

7:00 – 8:00      **1. Badging and Enrollment**      **ACMUI**

**OPEN SESSION**

8:00 – 10:15      **2. Opening Remarks**      **D. Bollock, NRC**  
Mr. Bollock will formally open the meeting and Mr. Collins will provide opening comments.      **D. Collins, NRC**

8:00 – 10:15      **3. Old Business**      **M. Smethers, NRC**  
Ms. Smethers will review past ACMUI recommendations and provide NRC responses.

8:00 – 10:15      **4. Open Forum**      **ACMUI**  
The ACMUI will identify medical topics of interest for further discussion.

8:00 – 10:15      **5. Event Reporting Mechanisms**      **ASTRO/AAPM, CARS, CRCPD, IAEA**  
Multiple organizations will discuss and share information related to their event reporting databases.

10:15 – 10:30      **BREAK**

10:30 – 11:30      **6. Medical Events Subcommittee Report**      **R. Ennis, ACMUI**  
Dr. Ennis will present the subcommittee's analysis of medical events for fiscal year 2015.

11:30 – 1:00      **LUNCH**

11:30 – 1:00      **7. Medical Event Reporting for All Modalities Excluding Permanent Implant Brachytherapy**      **J. Suh, ACMUI**  
Dr. Suh will discuss the subcommittee's recommendations for the reporting of medical events.

1:00 – 2:30      **8. 10 CFR Part 35 Rulemaking Update**      **T. Taylor, NRC**  
Ms. Taylor will provide an update on the 10 CFR Part 35 rulemaking effort.

1:00 – 2:30      **9. NRC Comments on 'Patient Intervention'**      **M. Fuller, NRC**  
Mr. Fuller will discuss staff's comments in response to the ACMUI's Patient Intervention Subcommittee Report.

2:30 – 3:00      **BREAK**

**CLOSED SESSION**

3:00 – 5:00      **10. Ethics Training**      **M. Clark, NRC**  
**11. INFOSEC Training**      **R. Norman, NRC**  
**12. Allegations Training**      **S. Hawkins, NRC**

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|               | <b>13. Yttrium-90 Microspheres Brachytherapy Licensing Guidance</b><br>Dr. Tapp will provide an overview of the revisions to the Y-90 Microspheres Brachytherapy Licensing Guidance.<br>Dr. Metter will provide the subcommittee's comments on the proposed revisions. | <b>K. Tapp, NRC<br/>D. Metter, ACMUI</b>     |
| 8:00 – 10:15  | <b>14. NRC's Abnormal Occurrence Criteria Policy Statement Update</b><br>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><br>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><br>Representatives from Spectrum Pharmaceuticals, Inc. will discuss their proposed revisions to the T&E requirements for alpha and beta emitters.                                | <b>Spectrum<br/>Pharmaceuticals, Inc.</b>    |
| 11:30 – 1:00  | <b>LUNCH</b>                                                                                                                                                                                                                                                           |                                              |
|               | <b>17. Worldwide Supply of Molybdenum-99</b><br>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><br>Dr. Howe will provide an overview of the 10 CFR 35.1000 licensing guidance drafted by an NRC/OAS working group.<br>Dr. Dilsizian will provide the subcommittee's comments on the proposed guidance.               | <b>DB. Howe, NRC<br/>V. Dilsizian, ACMUI</b> |
| 2:30 – 3:00   | <b>BREAK</b>                                                                                                                                                                                                                                                           |                                              |
|               | <b>19. Germanium-68/Gallium-68 Medical Use Generator Licensing Guidance</b><br>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><br>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><br>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**