

MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

September 29-30 2014
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.

Monday, September 29, 2014
OPEN SESSION

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| 8:30 – 8:45 | 1. Opening Statements
Mr. Fuller will formally open the meeting and Ms. Dudes will provide opening comments. | M. Fuller, NRC
L. Dudes, NRC |
| 8:45 – 9:00 | 2. Old Business
Ms. Holiday will review past ACMUI recommendations and provide NRC responses. | S. Holiday, NRC |
| 9:00 – 9:45 | 3. Physical Presence Requirements for Perfexion™
Dr. Suh and Dr. Howe will discuss the existing physical presence requirements for the Leksell Gamma Knife® Perfexion™ licensed under 10 CFR 35.1000. | J. Suh, ACMUI
D. Howe, NRC |
| 9:45 – 10:00 | B R E A K | |
| 10:00 – 10:30 | 4. Licensing Under 10 CFR 35.1000
Ms. Holiday will provide information on how NRC determines which emerging medical technologies are licensed under 35.1000 and how licensing guidance is developed. | S. Holiday, NRC |
| 10:30 – 11:30 | 5. Y-90 Microspheres ME Subcommittee Report
Dr. Guiberteau will discuss the subcommittee's recommendations regarding the current medical event reporting criteria for yttrium-90 microspheres. | M. Guiberteau, ACMUI |
| 11:30 – 1:00 | L U N C H | |
| 1:00 – 1:30 | 6. FDA's Role in the Global Mo-99 Shortage
Dr. Suleiman will discuss the FDA's role related to the global shortage of molybdenum-99. | O. Suleiman, ACMUI |
| 1:30 – 1:45 | 7. ACMUI Bylaws
Dr. Zanzonico will discuss the proposed revisions to the ACMUI bylaws. | P. Zanzonico, ACMUI |
| 1:45 – 2:20 | 8. Release of Patients Administered Radionuclides
Dr. Howe will provide an update on the staff's efforts related to the release of patients administered radioactive material. | D. Howe, NRC |
| 2:20 – 2:30 | 9. Follow-up to the May 2014 ACMUI Commission Meeting
Ms. Holiday will discuss the direction received from the Commission following its meeting with the ACMUI on May 9, 2014. | S. Holiday, NRC |

2:30 – 3:00 **10. Enhancing Interactions Between the NRC and the Medical Community** **S. Langhorst, ACMUI**
Dr. Langhorst will discuss possible mechanism to enhance the relationship and interactions between the NRC and the medical community.

3:00 – 3:30 **B R E A K**

3:30 – 4:15 **11. Safety Culture: Interactions Between Licensees and Regulators** **S. Langhorst, ACMUI**
Dr. Langhorst will expand upon the discussion from the May 9, 2014 ACMUI Commission Meeting regarding safety culture.

4:15 – 5:00 **12. Medical Events Subcommittee Report** **J. Welsh, ACMUI**
Dr. Welsh will discuss the subcommittee report on medical events for fiscal year 2013.

Tuesday, September 30, 2014
OPEN SESSION

8:00 – 9:30 **13. Event Reporting Mechanisms** **ASTRO/AAPM, CRCPD, ROIR, SAFRON**
Multiple organizations will discuss and share information related to their event reporting databases.

9:30 – 10:00 **14. Publicly Available NMED** **A. McIntosh, NRC**
Ms. McIntosh will discuss the public availability of the NRC's event reporting database system; the Nuclear Materials Event Database (NMED).

10:00 – 10:15 **B R E A K**

10:15 – 10:30 **15. Special Presentation to Dr. Welsh** **B. Holian, NRC**
Mr. Holian will make a special presentation to Dr. Welsh for his years of service on the ACMUI and to the NRC.

10:30 – 10:45 **16. Remarks from Dr. Welsh** **J. Welsh, ACMUI**
Dr. Welsh will provide his perspectives about serving on the ACMUI.

10:45 – 11:00 **17. Administrative Closing** **S. Holiday, NRC**
Ms. Holiday will provide a meeting summary and propose dates for the next meeting.

11:00 – 12:30 **L U N C H**
CLOSED SESSION

12:30 – 1:00 **18. INFOSEC Training** **R. Norman, NRC**
1:00 – 1:30 **19. Allegations Training** **TBD, NRC**
1:30 – 2:00 **20. Ethics Training** **ETHICS Team, NRC**

2:00 **A D J O U R N**