

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

- | | | |
|---------------|---|---|
| 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 Dr. Langhorst will discuss possible mechanism to enhance the relationship and interactions between the NRC and the medical community.	S. Langhorst, ACMUI
-------------	--	----------------------------

3:00 – 3:30	B R E A K
-------------	------------------

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

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

Tuesday, September 30, 2014	
OPEN SESSION	

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

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

10:00 – 10:15	B R E A K
---------------	------------------

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

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

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

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
------	----------------------