

MEETING AGENDA

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

April 15-16, 2013
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, April 15, 2013

CLOSED SESSION

8:00 – 8:15	1. HRMS Training	S. Holiday, NRC
8:15 – 8:30	2. eTravel Training	S. Holiday, NRC
8:30 – 9:30	3. Biennial Evaluations and Discussion	S. Holiday, NRC

OPEN SESSION

9:30 – 9:45	4. Opening Statements	C. Einberg & B. McDermott, NRC
	Mr. Einberg will formally open the meeting and Mr. McDermott will provide opening comments.	

9:45 – 10:00	5. Special Presentation	Chairman A. McFarlane, NRC
	Chairman Allison McFarlane will make a special presentation to Dr. Malmud.	

10:00 – 10:15	6. Old Business	A. Cockerham, NRC
	Ms. Cockerham will review past ACMUI recommendations and provide NRC responses.	

10:15 – 10:30	7. ACMUI Webpage Update	A. Cockerham, NRC
	Ms. Cockerham will discuss the revisions made to the ACMUI webpage.	

10:30 – 11:00 B R E A K

11:00 – 12:00	8. Draft Guidance for 10 CFR Part 35 Rulemaking	NRC Staff
	Staff from the medical team and the ACMUI will discuss the draft guidance for the expanded 10 CFR Part 35 rulemaking.	ACMUI

12:00 – 1:30 L U N C H

1:30 – 2:30	9. Draft Guidance for 10 CFR Part 35 Rulemaking (cont.)	NRC Staff
	Staff from the medical team and the ACMUI will discuss the draft guidance for the expanded 10 CFR Part 35 rulemaking.	ACMUI

2:30 – 3:00 B R E A K

3:00 – 5:00	10. AO Subcommittee Report	S. Langhorst, ACMUI
	Dr. Langhorst will discuss the Abnormal Occurrence Subcommittee Report.	

Tuesday, April 16, 2013
OPEN SESSION

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| 8:00 – 8:30 | 11. 10 CFR Part 35 Rulemaking Update.
Ms. Bhalla and Mr. Lohr will provide an update on the status of rulemaking for 10 CFR Part 35 | N. Bhalla & E. Lohr, NRC |
| 8:30 – 9:00 | 12. Status of Data Collection on Patient Release
Dr. Saba will provide an update on the status of patient release. | M. Saba, NRC |
| 9:00 – 9:30 | 13. The NNSA's Efforts to Minimize the Use of Highly Enriched Uranium in Molybdenum-99 Production
Dr. Staples and Ms. Hamilton will provide an overview of efforts to minimize moly-99 production from HEU. | P. Staples, NNSA
R. Hamilton, NNSA |
| 9:30 – 10:00 | 14. The Federal Government's Center for Medicare and Medicaid Service's (CMS) 2013 Reimbursement Policy for non-HEU Produced Medical Isotopes
Dr. Duvall will provide an overview of the reimbursement policy for non-HEU produced medical isotopes, including Moly-99. | D. Duvall, HHS |
| 10:00 – 10:30 | B R E A K | |
| 10:30 – 11:00 | 15. Medical Related Events
Dr. Howe will provide the latest information on medical-related events. | DB Howe, NRC |
| 11:00 – 11:30 | 16. Thyroid Cancer Survivors' Conference
Ms. Weil will provide an overview of her experience at the ThyCa Conference. | L. Weil, ACMUI |
| 11:30 – 12:00 | 17. Germanium-68/Gallium-68 Generator, Clinical Uses and Regulatory Issues
Mr. Mattmuller will discuss impacts on the medical community. | S. Mattmuller, ACMUI |
| 12:00 – 12:30 | 18. Status of Licensing Guidance for ViewRay™
Dr. Gabriel and Ms. Holiday will provide a status update of the licensing guidance development for the ViewRay™ System. | S. Gabriel, NRC
S. Holiday, NRC |
| 12:30 – 1:30 | L U N C H | |
| 1:30 – 2:00 | 19. Outgoing Remarks from Dr. Malmud
Dr. Malmud will provide outgoing remarks to the ACMUI and NRC. | L. Malmud, ACMUI |
| 2:00 – 2:30 | 20. Administrative Closing
Ms. Holiday will provide a meeting summary and propose dates for the next meeting. | S. Holiday, NRC |

2:30

A D J O U R N