

# 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 | <b>1. HRMS Training</b>                       | <b>S. Holiday, NRC</b> |
| 8:15 – 8:30 | <b>2. eTravel Training</b>                    | <b>S. Holiday, NRC</b> |
| 8:30 – 9:30 | <b>3. Biennial Evaluations and Discussion</b> | <b>S. Holiday, NRC</b> |

#### OPEN SESSION

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|---------------|---|---|
| 9:30 – 9:45   | <b>4. Opening Statements</b><br>Mr. Einberg will formally open the meeting and Mr. McDermott will provide opening comments. | <b>C. Einberg &amp; B. McDermott, NRC</b> |
| 9:45 – 10:00  | <b>5. Special Presentation</b><br>Chairman Allison McFarlane will make a special presentation to Dr. Malmud.                | <b>Chairman A. McFarlane, NRC</b>         |
| 10:00 – 10:15 | <b>6. Old Business</b><br>Ms. Cockerham will review past ACMUI recommendations and provide NRC responses.                   | <b>A. Cockerham, NRC</b>                  |
| 10:15 – 10:30 | <b>7. ACMUI Webpage Update</b><br>Ms. Cockerham will discuss the revisions made to the ACMUI webpage.                       | <b>A. Cockerham, NRC</b>                  |

#### 10:30 – 11:00 B R E A K

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|---------------|--|--------------------------|
| 11:00 – 11:15 | <b>8. Status of Data Collection on Patient Release</b><br>Dr. Saba will provide an update on the status of patient release.  | <b>M. Saba, NRC</b>      |
| 11:15 – 11:45 | <b>9. Thyroid Cancer Survivors' Conference</b><br>Ms. Weil is provide an overview of her experience at the ThyCa Conference. | <b>L. Weil, ACMUI</b>    |
| 11:45 – 12:00 | <b>10. Licensing of Radium-223</b><br>Ms. Cockerham will discuss the licensing of Ra-223 Dichloride.                         | <b>A. Cockerham, NRC</b> |

#### 12:00 – 1:30 L U N C H

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|-------------|--|-------------------------------------|
| 1:30 – 2:30 | <b>11. Medical Related Events</b><br>Dr. Howe will provide the latest information on medical-related events.   | <b>DB Howe, NRC</b>                 |
| 2:30 – 3:00 | <b>12. Interim Enforcement Policy for Permanent Implant Brachytherapy Programs</b><br>Dr. Zelac will discuss the interim enforcement policy for permanent implant brachytherapy. | <b>R. Zelac, NRC</b>                |
| 3:00 – 3:30 | <b>13. 10 CFR Part 35 Rulemaking Update.</b><br>Ms. Bhalla and Mr. Lohr will provide an update on the status of rulemaking for 10 CFR Part 35                                    | <b>N. Bhalla &amp; E. Lohr, NRC</b> |

#### 3:30 – 4:00 B R E A K

4:00 – 5:00 **14. Draft Guidance for 10 CFR Part 35 Rulemaking** **NRC**  
Staff from the medical team and the ACMUI will discuss **ACMUI**  
the draft guidance for the expanded 10 CFR Part 35 rulemaking.

**Tuesday, April 16, 2013**  
**OPEN SESSION**

8:00 – 8:30 **15. Status of Licensing Guidance for ViewRay™** **S. Gabriel, NRC**  
Dr. Gabriel and Ms. Holiday will provide a status update of **S. Holiday, NRC**  
the licensing guidance development for the ViewRay™ System.

8:30 – 9:00 **16. Germanium-68/Gallium-68 Generator, Clinical Uses and Regulatory Issues** **S. Mattmuller, ACMUI**  
Mr. Mattmuller will discuss impacts on the medical community.

9:00 – 9:30 **17. The NNSA's Efforts to Minimize the Use of Highly Enriched Uranium in Molybdenum-99 Production** **P. Staples, NNSA**  
Dr. Staples and Ms. Hamilton will provide an overview of efforts **R. Hamilton, NNSA**  
to minimize moly-99 production from HEU.

9:30 – 10:00 **18. The Federal Government's Center for Medicare and Medicaid Service's (CMS) 2013 Reimbursement Policy for non-HEU Produced Medical Isotopes** **D. Duvall, HHS**  
Dr. Duvall will provide an overview of the reimbursement policy for non-HEU produced medical isotopes, including Moly-99.

10:00 – 10:30 **B R E A K**

10:30 – 12:30 **19. AO Subcommittee Report** **S. Langhorst, ACMUI**  
Dr. Langhorst will discuss the Abnormal Occurrence Subcommittee Report.

12:30 – 1:30 **L U N C H**

1:30 – 2:00 **20. Outgoing Remarks from Dr. Malmud** **L. Malmud, ACMUI**  
Dr. Malmud will provide outgoing remarks to the ACMUI and NRC.

2:00 – 2:30 **21. Administrative Closing** **S. Holiday, NRC**  
Ms. Holiday will provide a meeting summary and propose dates for the next meeting.

2:30 **A D J O U R N**