

**AGENDA
ACMUI MEETING
APRIL 20-21, 2005**

WEDNESDAY APRIL 20, 2005, MARRIOTT BETHESDA, NORTH, ROCKVILLE, MARYLAND

(Room location to be announced in reader boards throughout the hotel)

- 1) 8:00 – 8:05 Opening Remarks (Open Session)
(Presenter: T. Essig, NRC)
Mr. Essig will formally open the meeting.
- 2) 8:05 – 8:10 Opening Remarks (Open Session)
(Presenter: C. Miller, PhD, NRC)
Dr. Miller will provide opening remarks.
- 3) 8:10 – 9:00 Commission Briefing Preparation (Open Session)
(Presenters: Dr. Eggli, Dr. Vetter, and Dr. Williamson)
Presenters will use this time to will review their briefing to the Commission.
- 4) 9:00 - 10:00 ACMUI Review of Medical Events Involving I-131 (Open Session)
(Presenter: Dr. Eggli, ACMUI)
The ACMUI will provide the NRC staff its advice, recommendations, and insights regarding the cause of medical events involving I-131, and possible methods to reduce them.
- 10:00 – 10:15** *****BREAK*****
- 5) 10:15 - 11:00 Case Experience Using I-125 Seeds as Markers (Open Session)
(Presenter: R. Vetter, PhD, ACMUI)
Dr. Vetter will present some actual findings from the use of I-125 seeds as markers for tumors, as experienced by Mayo Clinic.
- 6) 11:00 – 12:00 FDA Radiation Dose Limits for Human Research Subjects Using Certain Radiolabeled Drugs: Adults and Children (Open Session)
(Presenter: Orhan Suleiman, PhD, ACMUI)
Dr. Suleiman, the Food and Drug Administration representative to the ACMUI, will give a briefing designed to explain the the current FDA thinking in terms of human research issues; specifically radiation dose limits, for a certain class of radio labeled drugs.
- 12:00 – 1:00** *****LUNCH*****

- 7) 1:00 – 2:00 Establishing Guidance on Exceeding Dose Limits for Members of the Public (Open Session)
(Presenters: S. Sherbini, PhD, NRC; Ralph Lieto, ACMUI)
Dr. Sherbini will present the staff's proposed guidance that will allow members of the public to exceed the regulatory dose limit in instances where a family member is caring for an ill relative. Mr. Lieto will also present his views.
- 8) 2:00 – 2:30 Status of Rulemaking, Part 35 - Training and Experience
(Open Session) (Presenter: R. Broseus, Phd.,NRC)
Dr. Broseus will update the ACMUI on the progress of the Pt. 35 rulemaking.
- 9) 3:15 – 4:45 Commission Briefing (Open Session)
(Presenters: Dr. Eggli, Dr. Vetter, and Dr. Williamson)
Presenters will provide the Commission with a status update on the efforts of the ACMUI to recommend changes to the medical event criteria definition (Williamson); provide ACMUI opinions on the recently revised training and experience criteria for specialty board recognition (Eggli); provide an overview of its recommendations to the ICRP 60's 2005 recommendations (Vetter); and provide ACMUI opinions on the staff's report on dose reconstruction, as reported in SECY 04-0107 (Williamson).

4:45

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THURSDAY APRIL 21, 2005 MARRIOTT BETHESDA, NORTH, ROCKVILLE, MARYLAND

(Room location to be announced in reader boards throughout the hotel)

- 10) 8:00 – 8:30 ACMUI Biennial Self-Evaluation (Closed Session)
The ACMUI will formulate responses to its required biennial self-evaluation.
- 11) 8:30 - 9:00 Personnel Matters (Closed Session)
- 12) 9:00 - 10:00 Protective Measures for Control of Sources:(Closed Session)
(Presenter: Gary Purdy, NSIR)
Mr. Purdy, NRC/NSIR, will provide the ACMUI with an update on the Agency's security measures for the control of radioactive sources.

NOTE: The above session may be closed pursuant to See 5 U.S.C. 552b (c) (3) to discuss unclassified safeguards information

10:00 – 10:15 *BREAK*****

- 13) 10:15 – 12:00 Status and Update: Redefining Medical Events (Open Session)
(Presenter: Dr. Williamson, ACMUI)
Dr. Williamson will lead the discussion that will forward to NRC staff the ACMUI's recommendation(s) and risk insights regarding updating the definition of medical events in 10 CFR Part 35.

12:00 – 1:00 *LUNCH*****

- 14) 1:00 – 2:00 Patient Safety Issues with Gamma Stereotactic Radiosurgery
(Open Session) (Presenter: Douglas Kondziolka, MD; International Radiosurgery Association (IRSA))
Dr. Kondziolka will present IRSA's views and recommendations on physician presence and responsibilities during gamma stereotactic radiosurgery.
- 15) 2:00 – 3:00 The Importance Of Radiation Oncologist Presence and Authorized User Status for Gamma Stereotactic Surgery Procedures
(Open Session) (Presenter: David Larson, MD, ASTRO, former Chairman and Professor of Radiation Oncology and Neurology at the University of San Francisco.)
Dr. Larson will present the views of the American Society of Therapeutic Radiology and Oncology (ASTRO) regarding the necessity of the presence of radiation oncologists during gamma stereotactic radiosurgery, to include: the training the radiation oncologist receives to perform these modalities, the added benefits to patient safety with radiation oncologist as the authorized user, and the definition of radiosurgery.

3:00 – 3:15

*****BREAK*****

16) 3:15 – 4:15

Discussion: Physical Presence During Gamma Stereotactic Radiosurgery (Open Session)

Presenters from IRSA and ASTRO, as well as other interested parties in attendance, will use this time to further discuss their recommendations and perspectives on physical presence during gamma stereotactic radiosurgery.

17) 4:15 - 4:30

Administrative Closing/Action Item Review (Open Session)
(Open Session) (Presenter : Angela R. McIntosh)

The NRC staff and the ACMUI will review staff response to recommendations and action items from the Fall 2004 meeting; will discuss miscellaneous items of interest arising from the April 20-21, 2005 meeting; will review action items arising from the April 2005 meeting; will discuss other non-sensitive administrative matters related to committee business, if any; and will discuss proposed meeting dates for the Fall 2005 meeting.

4:30

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