

**AGENDA
ACMUI MEETING
OCTOBER 13-14, 2004**

**WEDNESDAY, OCTOBER 13, 2004, CONFERENCE ROOM, T-2B3, TWO WHITE FLINT NORTH,
ROCKVILLE, MARYLAND**

- 1) 8:00 – 8:15 Opening Remarks (Closed Session) (Presenter: C. Miller, PhD, NRC)
Dr. Miller will open the closed session with a status update of ACMUI/ NRC staff interactions, and will also provide an outline of the topics to be discussed during the closed session.
- 2) 8:15 – 8:45 Ethics Briefing (Closed Session) (Presenter: J. Szabo, NRC)
Mr. Szabo, Office of the General Counsel, will provide the ACMUI its required annual ethics briefing.
- 3) 8:45 – 9:45 Administrative Issues (Closed Session) (Presenter: T. Essig, NRC)
Mr. Essig will brief the ACMUI on issues related to committee management, logistics, and the roles and responsibilities of the ACMUI and the NRC staff.
- 4) 9:45 – 10:15 Interim Source Database (Closed Session) (Presenter: W. Ward, NRC)
Mr. Ward will brief the ACMUI on the purpose and the status of the interim radioactive source database.

NOTE: The above sessions may be closed pursuant to 5 U.S.C. 552b(c)(2), (6) and (9)(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.”

10:15 – 10:30 *BREAK*****

- 5) 10:30 - 10:35 Opening Remarks (Open) (Presenter: T. Essig, DFO, NRC)
Mr. Essig, Designated Federal Officer, ACMUI, will commence the open session with introductory remarks explaining the purpose of the meeting and welcoming all in attendance.
- 6) 10:35 – 11:05 Radioimmunotherapy and Microsphere Therapy (Open)
(Presenter: D.B. Howe, PhD, NRC)
Dr. Howe will discuss current NRC policy, regulations, and training and experience (T&E) requirements regarding antibody-linked radionuclide therapy and microsphere therapy.

- 7) 11:05 – 12:00 Radioimmunotherapy and Microsphere Therapy (Open)
(Presenter: S. Nag, MD, ACMUI)
Dr. Nag will present his views on issues regarding regulation of these therapies.
- 12:00 – 1:00** *****LUNCH*****
- 8) 1:00 – 1:30 Registration of Brachytherapy Sources (Open) (Presenter: T. Harris)
Mr. Harris will discuss the background on existing registration of brachytherapy seeds and current guidance.
- 9) 1:30 – 2:00 Radiation Safety Aspects of I-125 Therapeutic Seeds Used as Markers in Breast Cancer Tumors (Open) (Presenter: Robert Gallagher, Mass.)
Mr. Gallagher will discuss the regulatory issues encountered with the off-label use of I-125 radioactive seeds as markers to delineate tumors in breast cancer patients.
- 10) 2:00 – 3:00 Staff Findings and Followup to the ACMUI Report on the NRC Method of Dose Reconstruction (Open) (Presenter: S. Sherbini, PhD, NRC)
Dr. Sherbini will present the NRC staff response to the ACMUI's recommendations related to the staff's method of reconstructing doses.
- 3:00 – 3:15** *****BREAK*****
- 11) 3:15 – 4:15 Status of Medical Events (Standing Item) (Open)
(Presenters: T. Essig, NRC; L. Gersey, NRC; and DB Howe, PhD, NRC)
Staff will seek the ACMUI's advice, recommendations, and insights regarding the cause of medical events, and possible methods to reduce them.
- 12) 4:15 – 5:00 Update to Medical Event Criteria Definition (Open)
(Presenter: R. Zelac, PhD, NRC)
Dr. Zelac will discuss possible efforts to update the medical event criteria definition.
- 5:00** **ADJOURN**

THURSDAY, OCTOBER 14 2004, CONFERENCE ROOM, T-2B3, TWO WHITE FLINT NORTH, ROCKVILLE, MARYLAND

- 13) 8:00 – 8:15 Draft Final 10 CFR 35 T&E: Status of Rulemaking (Open)
(Presenter: R. Broseus, PhD, NRC)
Dr. Broseus will brief the ACMUI with the status of the training and experience (T&E) draft final rule, which proposes the addition of specified training hours to the T&E.
- 14) 8:15 – 10:00 Discussion/Preparation of ACMUI Comment Letter on the Draft Final 10 CFR 35 T&E Rulemaking (Open)
The ACMUI will discuss the proposed changes as presented in the draft

final rule; reach consensus on ACMUI comments; and prepare a letter stating the committee's position on the draft final rule.

10:00 – 10:15

*****BREAK*****

15) 10:15 – 11:15

Proposed Changes to AO Criteria (Open) (Presenter: A. Jones, NRC)
Ms. Jones will present proposed changes to the Abnormal Occurrence criteria for the medical events.

16) 11:15 – 12:00

National Source Tracking (Open) (Presenter: M. Horn, NRC)
Ms. Horn will provide an overview of NRC's system to account for radioactive sources nationwide.

12:00 – 1:00

*****LUNCH*****

17) 1:00 – 3:00

2005 ICRP Recommendations (Open)
(Presenter: R. Vetter, PhD, ACMUI)
Dr. Vetter will brief the ACMUI on the International Commission on Radiological Protection's (ICRP) recommendations for 2005. Dr. Vetter will seek an ACMUI consensus position on the 2005 recommendations, for presentation to the ACNW Working Group discussion on October 19, 2004.

18) 3:00 – 3:30

Administrative Closing/Action Item Review (Open)
The NRC staff and the ACMUI will discuss miscellaneous items of interest arising from the October 13-14, 2004 meeting; will review action items arising from this meeting, will discuss other non-sensitive administrative matters related to committee business, if any; and will discuss proposed meeting dates for the Spring 2005 meeting.

3:30

ADJOURN