

TELECONFERENCE MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

December 15, 2011

MEETING SUMMARY

PURPOSE

To discuss the 2008 Advisory Committee on the Medical Uses of Isotopes (ACMUI) recommendations for Abnormal Occurrence (AO) medical event reporting criteria.

OUTCOME

The ACMUI endorsed their 2008 position, which is summarized by the following: AOs for medical licensees should be events which result in death or threaten life; AOs should not capture errors that are typically a function of treatment; AOs should be of significant adverse effect; AO criteria should be qualitative and not quantitative. The U.S. Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the ACMUI, as well as other stakeholders' views and opinions. The staff will consider these views in revising the AO criteria for medical licensees. The current AO criteria can be found in the *Federal Register* Volume 71 Number 197 Page 60200 dated October 12, 2006.

Full transcripts of the ACMUI meeting can be found on NRC's public website:

<http://www.nrc.gov/reading-rm/doc-collections/acmui/tr/>

Handouts from the ACMUI meeting can be found on NRC's public website:

<http://www.nrc.gov/reading-rm/doc-collections/acmui/meeting-slides/>

Final ACMUI Permanent Implant Brachytherapy Report can be found on NRC's public website

under "Related Information": <http://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html>

ATTENDEES

ACMUI

Milton S. Guiberteau, M.D.	Member
Susan M. Langhorst, Ph.D.	Member
Leon S. Malmud, M.D.	Chairman
Steve R. Mattmuller	Member
Christopher J. Palestro, M.D.	Member
John H. Suh, M.D.	Member
Orhan H. Suleiman, Ph.D.	Member
Bruce R. Thomadsen Ph.D.	Vice Chairman
William A. Van Decker, M.D.	Member
Laura Weil	Member
James S. Welsh, M.D.	Member
Pat Zanzonico, Ph.D	Member

NRC

Chris Einberg	Designated Federal Officer and Chief, Radioactive Materials Safety Branch
Michael Fuller	Alternate Designated Federal Officer and Medical Radiation Safety Team Leader
Ashley Cockerham	Alternate Designated Federal Officer and ACMUI Coordinator
Susan Chidakel	NRC staff
Said Daibes, Ph.D.	NRC staff
Latischa Hanson	NRC staff
Bill Maier	NRC staff
Angela McIntosh	NRC staff
Joe Nick	NRC staff
Gretchen Rivera-Capella	NRC staff
John Tomon	NRC staff
Ronald Zelac, Ph.D.	NRC staff

MEMBERS OF THE PUBLIC:

William Davidson	University of Pennsylvania
Lynne Fairobent	American Association of Physicists in Medicine
Dr. James Harvey	Northstar
Dr. Thomas Huston	Veterans Health Administration
Karen Langley	University of Utah
Larry Langrill	MidMichigan Medical Center
Janette Merrill	Society of Nuclear Medicine
Ralph Lieto	St. Joseph Mercy Hospital
Joseph Rodgers	Theragenics Corporation
Michael Sheetz	University of Pittsburgh
Cindy Tomlinson	American Society for Radiation Oncology

AGENDA TOPIC

1. Abnormal Occurrence Medical Event Criteria

RECOMMENDATIONS AND ACTIONS

The ACMUI confirmed their recommendation from 2008 with one amendment. The criteria below was revised to indicate more than one physician could be consulted. The final recommendation read, as follows:

An Abnormal Occurrence is a medical event that results in a) death; or b) a significant impact on patient health that would result in permanent functional damage or a significant adverse health effect that would not have been expected from the normal treatment regimen, as determined by the NRC or Agreement State designated consultant physician(s).

The recommendation above was approved by the ACMUI with 11 favorable votes and one opposing vote.