

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

June 18, 2013

MEETING SUMMARY

PURPOSE

To discuss the Advisory Committee on the Medical Uses of Isotopes (ACMUI) subcommittee report analyzing yttrium-90 (Y-90) microsphere brachytherapy medical events for possible trends or areas of concern.

OUTCOME

The U.S. Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the ACMUI regarding Y-90 microsphere brachytherapy medical events. The staff will consider these views in its continuing effort to trend medical events involving Y-90 microspheres and to make the Microsphere Brachytherapy Sources and Devices guidance more useful, practical, and not overly burdensome on licensees, while maintaining public health and safety.

A full transcript and handout for the ACMUI meeting can be found on NRC's public website at <http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/>.

The final Yttrium-90 Microsphere Brachytherapy Medical Events Analysis Report can be found on NRC's public website at <http://www.nrc.gov/reading-rm/doc-collections/acmui/reports/>.

ATTENDEES

ACMUI

Milton S. Guiberteau, M.D.	Acting Chairman
Susan M. Langhorst, Ph.D.	Member
Steve R. Mattmuller	Member
Christopher J. Palestro, M.D.	Member
Orhan H. Suleiman, Ph.D.	Member
William Van Decker, M.D.	Member
Laura M. Weil	Member
James S. Welsh, M.D.	Member
Pat Zanzonico, Ph.D	Member
Jared Thompson	Agreement State Representative (stand-in, non-voting)

NRC

Brian McDermott	Director, Division of Materials Safety and State Agreements
Pamela Henderson	Deputy Director, Division of Materials Safety and State Agreements

Christian Einberg	Designated Federal Officer
Ashley Cockerham	Alternate Designated Federal Officer
Sophie Holiday	ACMUI Coordinator
Jennifer Bishop	NRC staff, Region III
Jackie Cook	NRC staff, Region IV
Sara Forster	NRC staff, Region III
Cassandra Frazier	NRC staff, Region III
Sandra Gabriel, Ph.D.	NRC staff, FSME
Bob Gallagher	NRC staff, Region I
Michelle Hammond	NRC staff, Region IV
Latischa Hanson	NRC staff, Region IV
Donna-Beth Howe, Ph.D.	NRC staff, FSME
Dennis O'Dowd	NRC staff, Region III
Randy Ragland	NRC staff, Region I
Gretchen Rivera-Capella	NRC staff, FSME
Lester Tripp	NRC staff, Region I

MEMBERS OF THE PUBLIC:

Dr. Maxwell Amurao – Columbia University
 Amanda Barriage – Nordion Incorporated
 Janet Bukovcan – Nordion, Incorporated
 Robert Dansereau – New York State Department of Health
 Susan Efler – Nordion, Incorporated
 Dr. Andrew Kang – US Food and Drug Administration
 Ralph Lieto – St. Joseph Mercy Hospital
 Steven Marsh – Baystate Health
 Scott McGhee – Nordion, Incorporated
 Andrew McKinley – American Society of Nuclear Cardiology
 Darren Perrero – Illinois Emergency Management Agency
 Michael Peters – American College of Radiology
 Gloria Romanelli – American College of Radiology
 Daniel Samson – New York State Department of Health
 Karen Sheehan – Fox Chase Cancer Center
 Michael Sheetz – University of Pittsburgh
 Daniel Snyder – Geisinger Health System
 Nancy Stanley – New Jersey Department of Environmental Protection
 Cindy Tomlinson – American Society for Radiation Oncology
 Ed Trukowski – New Jersey Department of Environmental Protection
 Gary E. Williams – Department of Veterans Affairs, National Health Physics Program

AGENDA TOPIC

Yttrium-90 Microsphere Brachytherapy Medical Events Analysis Report

SUMMARY

The ACMUI Medical Events Subcommittee reviewed medical events reported to the NRC since 2000 with a focus on events reported since 2007. The subcommittee evaluated the number of medical events reported along with the root causes and made comparisons to estimates of the number of procedures performed to determine incidence rates. During the teleconference, the

subcommittee provided a draft report for the ACMUI's consideration. The committee discussed training for Authorized Users and other individuals involved with the procedure; use of the devices; and other potential areas for error. The draft subcommittee report was endorsed by the full ACMUI.

RECOMMENDATIONS AND ACTIONS

The Draft Yttrium-90 Microsphere Brachytherapy Medical Events Analysis Report (ML13162A113) was unanimously approved by the ACMUI members present with minor grammatical revisions. The Final Yttrium-90 Microsphere Brachytherapy Medical Events Analysis Report (ML13175A025) was distributed on June 28, 2013.