

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

May 7-8, 2009

MEETING SUMMARY

PURPOSE

To discuss issues related to the implementation of the medical regulations in 10 CFR Part 35, "Medical Use of Byproduct Material."

OUTCOME

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) made recommendations, and 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 its continuing effort to make 10 CFR Part 35 more useful, practical, and not overly burdensome on licensees, while maintaining public health and safety.

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

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

ATTENDEES

ACMUI

Leon S. Malmud, M.D.	Chairman
Douglas F. Eggli, M.D.	Member
Darrell Fisher, Ph.D.	Member
Debbie Gilley	Member
Milton S. Guiberteau, M.D.	Representative
Ralph P. Lieto	Member
Steve R. Mattmuller	Member
Subir Nag, M.D.	Member
Orhan H. Suleiman, Ph.D.	Member
Bruce R. Thomadsen Ph.D.	Member
William A. Van Decker, M.D.	Member
Richard J. Vetter, Ph.D.	Member
James S. Welsh, M.D.	Member

NRC

Charlie Miller, Ph.D.	Director, Office of Federal and State Materials and Environmental Management Programs
Rob Lewis	Director, Division of Materials Safety and State Agreements
Chris Einberg	Designated Federal Officer
Cindy Flannery	Alternate Designated Federal Officer
Steven Baggett	NRC staff
Neelam Bhalla	NRC staff
Ashley Cockerham	NRC staff

NRC continued

Don Cool, Ph.D.	NRC staff
Leira Cuadrado	NRC staff
Cassandra Frazier	NRC staff
Sandy Gabriel	NRC staff
Donna-Beth Howe, Ph.D.	NRC staff
Doris Lewis	NRC staff
Ed Lohr	NRC staff
Patricia Pelke	NRC staff
Gretchen Rivera-Capella	NRC staff
Mark Schaffer	NRC staff
Mark Thaggard	NRC staff
Glenda Villamar	NRC staff
Darrel Wiedeman	NRC staff
Duane White	NRC staff
Ron Zelac, Ph.D.	NRC staff

MEMBERS OF THE PUBLIC

Gary Becker, M.D. (phone)	American Board of Radiology
Kevin Crowley, Ph.D.	National Academies of Science
Melissa Cacia (phone)	American Association of Clinical Endocrinologists
Robert Dansereau (phone)	State of New York
William Davidson (phone)	University of Pennsylvania
Richard Eaton	Medical Imaging and Technology Alliance
Lynne Fairobent	American Association of Physicist in Medicine
Bonnie Hamilton	MDS Nordion
Karen Langley (phone)	State of Utah
Matthew Mauro, M.D.	Society of Interventional Radiologists
Katrina Miller (phone)	American Association of Clinical Endocrinologists
Mike Peters	American College of Radiology
Doug Pfeiffer	American Association of Physicist in Medicine
Gloria Romanelli	American College of Radiology
Joe Rodgers (phone)	Theragenics
Riad Salem, M.D.	Society of Interventional Radiologists
Reed Selwyn, Ph.D.	Uniformed Services University of the Health Sciences
Brian Stainken, M.D.	Society of Interventional Radiologists
Daniela Stricklin, Ph.D.	National Academies of Science
Stephen Thomas, Ph.D. (phone)	N/A
Ken Thurston	Sirtex
Cindy Tomlinson (phone)	Society of Nuclear Medicine
Ann Warbick-Cerone	MDS Nordion
Emily Wilson	American Society for Radiation Oncology
Jennifer Young (phone)	American Association of Clinical Endocrinologists

AGENDA TOPICS

1. Opening Statements
2. Old Business
3. Medical Event Reporting to the International Nuclear Event Scale
4. Training and Experience Subcommittee Report on Interventional Radiologists as Authorized Users for Yttrium-90 Microspheres

5. Potential Changes to 10 CFR Part 35
6. Veterans Affairs Medical Events
7. National Academy of Sciences Report on Medical Isotope Production without the Use of Highly Enriched Uranium
8. Status of Current and Future 10 CFR Part 35 Rulemaking
9. Next Steps to Interact with the Medical Communities on Possible Revision to Radiation Protection Regulations and Guidance
10. National Council on Radiation Protection and Measurements Report 160 "Ionizing Radiation Exposure of the Population of the United States" and It's Implications for NRC Programs
11. Training and Experience Subcommittee Report on American Board of Radiology Certification
12. Subcommittee Report on Byproduct Material Events
13. Infiltrations of Therapeutic Radiopharmaceuticals as Medical Events
14. Outgoing Member Presentations
15. Administrative Closing
16. Commission Briefing Preparation and Self-Evaluations

RECOMMENDATIONS AND ACTIONS

For agenda topic 4, Training and Experience Subcommittee Report on Interventional Radiologists as Authorized Users for Yttrium-90 Microspheres, ACMUI made the following recommendation, which passed unanimously:

NRC staff should allow interventional radiologists to become Authorized Users for Yttrium-90 microspheres with:

- 1) 80 hours training in: a) radiation physics and instrumentation; b) radiation protection; c) mathematics pertaining to the use and measurement of radioactivity; d) chemistry of byproduct material for medical use; and e) radiation biology; and
- 2) work experience under the supervision of an Authorized User involving: a) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; b) checking survey meters for proper operation; c) examination of each individual; d) calculating, measuring, and safely preparing patient or human research subject dosages; e) using administrative controls to prevent a medical event involving the use of byproduct material; f) using procedures to control and to contain spilled byproduct material safely and using proper decontamination procedures; g) follow up and review of each patient's or human research subject's case history; and h) the operation of and quality management for dose calibrators; and
- 3) board certification in diagnostic radiology with a subspecialty in interventional radiology or three years supervised clinical experience in diagnostic radiology with one year in interventional radiology.

For agenda topic 5, Potential Changes to 10 CFR Part 35, ACMUI made the following two recommendations:

NRC staff should revise 35.390(b)(1)(ii)(G)(3) to read "parenteral administration requiring a written directive for any radionuclide that is being used primarily because of its beta emission, or low energy photo-emission, or auger electron; and/or" and revise 35.390(b)(1)(ii)(G)(4) to read

"parenteral administration requiring a written directive for any radionuclide that is being used primarily because of its alpha particle emission."

The recommendation passed with five favorable votes, four opposing votes and two abstentions.

NRC staff should revise 10 CFR 35.490 & 690 as proposed with one exception. Delete "private practice." The regulation should read "500 hours of work experience, under the supervision of an Authorized User who meets the requirements in [35.490 or 35.690] or equivalent Agreement State requirements at a medical institution or clinic..."

The recommendation passed with one abstention.

For agenda topic 6, Veterans Affairs Medical Events, ACMUI suggested every brachytherapy quality assurance program should include peer review, as published by the American Brachytherapy Society, and Authorized Users should perform post-implant dosimetry to prevent recurrence of events like those at the Veterans Affairs Medical Center.

This recommendation was tabled until ACMUI receives additional information from NRC staff.

For agenda topic 9, Next Steps to Interact with the Medical Communities on Possible Revision to Radiation Protection Regulations and Guidance, ACMUI created a subcommittee to review International Council on Radiation Protection Publication 103. The subcommittee includes: Dr. Bruce Thomadsen (chair), Ms. Debbie Gilley, and Dr. William Van Decker. The subcommittee will coordinate their review with Dr. Don Cool, NRC staff.

For agenda topic 10, National Council on Radiation Protection and Measurements (NCRP) Report 160 "Ionizing Radiation Exposure of the Population of the United States" and its Implications for NRC Programs, ACMUI came to a consensus that the report is believed to be scientifically sound and well-written. ACMUI believes NRC and Agreement States should collect and maintain dose records and keep ACMUI aware of the issues; however, NRC should continue a policy of not intervening in medical practice. ACMUI supports the medical principle of "First, do no harm" and expressed continued concern about exposure to children. ACMUI's current belief is that the benefit of medical procedures involving radiation outweighs the risk.

Three members abstained from supporting the aforementioned statements on NCRP Report 160 due to conflicts of interest. These individuals authored sections of NCRP Report 160.

For agenda item 11, Training and Experience Subcommittee Report on American Board of Radiology Certification (ABR), ACMUI endorsed the subcommittee report, which outlined a pathway for ABR candidates to achieve Authorized User status, since these candidates may experience a delay between the completion of Training and Experience and receipt of board certification.

The recommendation passed with nine favorable votes, one opposing vote, and one abstention.

For agenda item 13, Infiltrations of Therapeutic Radiopharmaceuticals as Medical Events, ACMUI recommended that NRC staff maintain the current policy and not require licensees to report therapeutic infiltrations as Medical Events.

The recommendation passed with nine favorable votes and two abstentions.