

MEETING OF THE
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

April 8, 2024

MEETING SUMMARY

PURPOSE

To discuss issues related to the implementation of the medical regulations in Title 10 of the *Code of Federal Regulations* (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 NRC 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 and handouts from the ACMUI meeting can be found on the NRC's ACMUI Meetings webpage, located at: <https://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/>. The meeting attendees are listed in Enclosure 1.

RECOMMENDATIONS AND ACTIONS

The following provides a summary of the discussions that took place on the topics on the ACMUI meeting agenda (Enclosure 2).

The ACMUI endorsed the following subcommittee report. This report and its recommendations can be viewed, in their entirety, on the NRC's ACMUI Subcommittee Reports webpage, located at the following link: <https://www.nrc.gov/reading-rm/doc-collections/acmui/reports/index.html>.

The ACMUI unanimously endorsed the report from the Subcommittee on Medical Events Report, as presented.

The ACMUI unanimously endorsed the report from the Subcommittee on Akesis Galaxy® RTi Draft Licensing Guidance, as presented.

The ACMUI unanimously endorsed the report from the Subcommittee on Yttrium-90 Microsphere Brachytherapy Sources and Devices Eye90 Microspheres® Licensing Guidance, as presented.

The ACMUI unanimously endorsed the report from the Subcommittee on LV Liberty Vision Corporation Yttrium-90 Disc and Iwand® Ophthalmic System Draft Licensing Guidance, as presented.

The following actions resulted from discussion that took place during the meeting.

The ACMUI recommended that the staff provide more information on root causes and corrective actions during their annual review of medical events and presentation to the Committee.

The ACMUI agreed that the current structure of reporting to the Office of Nuclear Material Safety and Safeguards continues to function effectively, and the meeting frequency is well-suited for the workload of the Committee.

Dr. Jadvar formed a subcommittee to review the Committee's bylaws regarding disclosures related to conflicts of interest. The subcommittee's membership includes Harvey Wolkov as chair, Rebecca Allen, Michael O'Hara, and Richard Green.

Dr. Jadvar formed a subcommittee to update the regulations in 10 CFR 30.35 that deal with financial assurance for Category 1 and Category 2 material. The subcommittee's membership includes Richard Green as chair, Richard Harvey, Harvey Wolkov, and Zoubir Ouhib .

Dr. Jadvar formed a subcommittee to reassess including an interventional radiologist in ACMUI membership. The subcommittee's membership includes Andrew Einstein as chair, Hossein Jadvar, Michael Folkert, Dr. Angle, and Rebecca Allen.

The ACMUI tentatively scheduled the fall 2024 meeting for October 7 - 8, 2024. After the meeting was adjourned the Committee decided to meet on November 4 - 5, 2024.

Enclosures:

1. Meeting Attendees
2. Meeting Agenda

MEETING ATTENDEES

April 8, 2024

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Hossein Jadvar, MD, PhD	Chair
Richard Green	Vice Chair
Richard Harvey, DrPh	Member
Josh Mailman	Member
Melissa Martin	Member
Michael D. O'Hara, PhD	Member
Zoubir Ouhib	Member
Megan Shober	Member
Harvey B. Wolkov, MD	Member
Andrew Einstein, MD	Member
Michael R. Folkert, MD, PhD	Member
Joanna R. Fair, MD, PhD	Member
John F. Angle, MD	Consultant to the Committee

NRC STAFF

Kevin Williams	Director, Division of Materials Safety, Security, State, and Tribal Programs (MSST)
Christian Einberg	Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer
Lillian Armstead	NMSS/MSST/MSEB and Designated Federal Officer
Celimar Valentin-Rodriguez	NMSS/MSST/MSEB
Aaron Thomlinson	NMSS/MSST/MSEB
Maryann Ayoade	NMSS/MSST/MSEB
Kenneth Brenneman	NMSS/MSST/MSEB
Daniel Dimarco	NMSS/MSST/MSEB
Cindy Flannery	NMSS/MSST/MSEB

Vincent Holahan	NMSS/MSST
Daniel Shaw	NMSS/MSST/MSEB
Sarah Spence	NMSS/MSST/MSEB
Katherine Tapp	NMSS/MSST/MSEB
Janice Nguyen	R-I/DRSS/MLAB
Travis Jones	OGC/LHE/MFW
Brian Allen	RES/DSA/RPB
Latischa Hanson	R-IV/DRSS/MLB
Jason VonEhr	R-I/DRSS/MLAB

PUBLIC PARTICIPANTS

Bill Erwin
Patrick Turner
Ralph Lieto
Kaci Studer
Clair Drozd
Ian Irvin
Stanley D. Hampton
Todd Senglaub
Sandy Gabriel
David Pellicciarini
David Crowley
Sean O. Wilson
Matt Hendrickson
Sean Chapel
Carol Wen
Cindy Tomlinson
Brenna Kettlewell

Daisy Coffman
Mary Burkhart
Michael A. Welling
Ariel Doucet
Kim C. Wiebeck
Melonie Paige
Olusegun A. Larinde
Richard Peros
Karen Flanigan
Dave Adler
Ron Parsons
Adam Ekstedt
Ashley Cockerham
Matthew Greenwood
Jonathan J. Otten
Mary Ann Spiker
Gabriel J. Munoz
Billie Harvey
Cindi L. Gilbert
B. Harvey
Brian M. Kelley
Tara Medich
Andrew Zimnoch
Sandra M. Ramirez
Michelle D. DeLeon
Mike N. Stephens
Georgia Lawrence
Christopher Lease

Jennifer Gersman

Diana Thompson

Cami Still

Arthur R. Schleipman

Manuel Diaz

Daniel Januseski

Emily C. Rostel

Alec Donahue

Andrea Armstrong

Wendy K. Galbraith

David Schlesinger

Michael Peters

Kaci Studer

Stanley D. Hampton

David Crowley

Sandy Gabriel

Sean O. Wilson

Michael A. Welling

Melonie Paige

Dave Adler

Brandi Woods

Michael Peters

Chris Eastlee

MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
April 8 – 9 2024

One White Flint North Building, 11555 Rockville Pike, Commissioner’s Hearing Room
North Bethesda, Maryland 20852

NOTE: Sessions of the meeting may be closed pursuant to 5 U.S.C. 552(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.

Monday, April 8, 2024
OPEN SESSION

8:30 – 8:45	1. Opening Remarks Mr. Einberg will formally open the meeting and Mr. Williams will provide opening remarks.	C. Einberg, NRC K. Williams, NRC
8:45 – 9:00	2. Old Business Ms. Armstead will review past ACMUI recommendations and provide NRC responses.	L. Armstead, NRC
9:00 – 9:15	3. Open Forum The ACMUI will identify medical topics of interest for further discussion.	ACMUI
9:15 – 10:45	4. Medical Related Events Mr. Dimarco will provide an update on recent medical events.	D. Dimarco, NRC
10:45 – 11:15	5. Akesis Galaxy RTi Unit Subcommittee Report Dr. Wolkov will discuss the subcommittee’s comments and recommendations on the NRC’s draft licensing guidance for the Akesis Galaxy RTi unit.	H. Wolkov, ACMUI
11:15 – 11:45	6. A Review of Prescription Error Reduction Methods Mr. Green will review seven published articles on error reduction methodologies and their relative success and value.	R. Green, ACMUI
11:45 – 1:00	LUNCH	
1:00 – 1:45	7. Eye90 Microsphere Device Subcommittee Report Dr. Folkert will discuss the subcommittee’s comments and recommendations on the NRC’s draft licensing guidance for the Eye90 microsphere device.	M. Folkert, ACMUI
1:45 - 2:30	8. Medical Events Subcommittee Report Dr. Harvey will review medical events reported to the NRC from fiscal years 2021-2023.	R. Harvey, ACMUI
2:30 - 3:15	9. Medical Team Updates Dr. Valentin-Rodriguez will provide an update on the Medical Radiation Safety Team’s activities.	C.Valentin-Rodriguez, NRC
3:15 – 3:30	BREAK	

3:30 – 4:00	10. Liberty Vision Y-90 Episcleral Brachytherapy Source Subcommittee Report Mr. Ouhib will discuss the subcommittee’s comments and recommendations on the NRC’s draft licensing guidance for the LV Liberty Vision Y-90 Episcleral Brachytherapy Source.	Z. Ouhib, ACMUI
4:00– 4:15	11. ACMUI Reporting Structure Ms. Armstead will provide an overview of the current reporting structure. Members will discuss the reporting structure of the Committee and provide feedback to the NRC.	L. Armstead, NRC
4:15 – 4:30	12. Open Forum The ACMUI will discuss medical topics of interest previously identified.	ACMUI
4:30 – 4:45	13. Administrative Closing Ms. Armstead will provide a meeting summary and propose dates for the fall 2024 meeting.	L. Armstead, NRC
4:45	BREAK (public portion ends)	
Tuesday, April 9, 2024 Open Session		
10:00 – 12:00	14. Commission Meeting with the ACMUI The ACMUI will brief the Commission on various topics in a public meeting.	ACMUI
	15. Group Photo The ACMUI will take a group photo with and without the Commission.	ACMUI
12:00	ADJOURN	