

MEETING OF THE  
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

June 17, 2024

**MEETING SUMMARY**

**PURPOSE**

To review and provide feedback and recommendations on the U.S. Nuclear Regulatory Commission (NRC) staff's draft proposed rule, associated draft implementation guidance, and draft model procedures for reporting nuclear medicine injection extravasations as medical events.

**OUTCOME**

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 the ACMUI's comments and recommendations prior to finalizing the meeting document.

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 following addendums were made to the subcommittee report as resulted from discussion that took place during the meeting.

The ACMUI recommended that the subcommittee report be clarified that their recommendation was that the NRC should not be making requirements about informed consent and not a general recommendation about informed consents.

The ACMUI also added the recommendation to replace the term "potential" with either "likely" or "expected" in the proposed rule.

The ACMUI unanimously endorsed, with one abstention, the subcommittee report with the addendums. 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>.

Enclosures:

1. Meeting Attendees
2. Meeting Agenda

## MEETING ATTENDEES

June 17, 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
Rebecca Allen	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
Celimar Valentin-Rodriguez	NMSS/MSST/MSEB and Designated Federal Officer
Lillian Armstead	NMSS/MSST/MSEB and Designated Federal Officer
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
Sarah Lopas	NMSS/REFS

## **PUBLIC PARTICIPANTS**

John Rumson

Josh Knowland

Lingyun Chen

Mateo Kajic

Christopher M. Helstern

Claire Drozd

Lynes Matos

Christopher M. Helstern

Carol Marcus

Jenni Johnston

James Norweck

Deirdre H. Elder

Chris Mitchell

Deborah M. Barrickman

Todd Senglaub

Ralph Lieto

Noelle Geier

Manuel Diaz

Emily C Rostel

Ike Hall

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Jenny Parra

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Wendy W. Terrenoire  
Michael Roberson  
Lisa Marie Guarino  
Carmine M. Plott  
Karen Burgard  
Doug Burrichter  
Jennifer A. Schroeder  
Jennifer Papich  
Douglas L. Miller  
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Leelavathi Sreenivas  
Rebecca Maxey  
Marie S. Hubbard  
Mike Drelich  
Michael Sheetz  
Joshua Johnson

Holli Allen  
Cathy Cutler  
Kim C. Wiebeck  
Adam C. Quinton  
Stephen Holmes  
Christopher Pagan  
Jonathan D. Moore  
Shawn Seeley  
Tony Gonzalez  
David Bierman  
Isabella Aristeguieta Pirela  
Erik Lyons  
Erin Grady  
Samantha Everett  
Alexus Willis  
Michael Peters  
Phillip Peterson  
Jessica Rodgers  
Jonathan J. Otten  
William Hinchcliffe  
Tim David Kleyn  
Ann Marie Derby  
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David Pellicciarini  
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Christopher L. Ogan  
Jussi Sillanpaa  
Jason D. Hout  
Tim Turkington  
Amol Patil  
Kelly N. Lewis  
Daniel Chiappetta  
Matt Wait  
Andrew Hoy  
Miguel de la Guardia  
Olga Stafford  
Helen Nadel  
Ashley Cockerham  
Deb Lemay  
Stephanie Aranki  
Laura M. Knox  
Erin Desemple  
Kyle K. Underwood  
Brad K.  
Emma Anderson  
Kayla Vom Dorp  
Edward Case  
Jaime A. Barnes  
Neil Petry

Will R. Gibbons

Sebastien Gros

Neil Whiteside

Hillary K. Haskins

Virginia Pappas

Emma Duncan

David Crowley

Matt Reiter

Joshua Young

Justin L. Brown

Cathey Rivers

Heather A. Jacene

Cami Still

Luke Schwartz

Casey Schmitz

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Scott Fuller

Jill Shepherd

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Paula Lang  
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Ramon Li  
Matt Dennis  
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Curtis Liddle  
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David M. Schuster  
Becki Harisis  
Jimmy Uhlemeyer  
Sandra M. Ramirez  
Kathleen Hintenlang  
Robin Elliott  
Jackie Cook  
Stanley D Hampton  
Elizabeth Franklin  
Brian M. Kelley  
William C. Chen  
Tim Turkington

Yuanqing Guo

Barbara Hamrick

John P. Metyko

Matthew Williamson

Sandy Gabriel

Christopher D. Nation

Ed Leidholdt

Rachel Nichols

Jennifer R. House

Rich Anderson

Robin Elliott

Sussie DeMello

Vineetha Ram

Susan Corey

Mandie S. Hubbard

Ed Nicho

**Court Reporter**

Emma Bower

**Advisory Committee on the Medical Uses of Isotopes  
TELECONFERENCE AGENDA  
Monday, June 17, 2024  
2:00 PM – 4:00 PM ET**

**OPEN SESSION**

2:00 PM -  
4:00PM

- 1. Opening Remarks** **C. Einberg, NRC**  
Mr. Christian Einberg will formally open the meeting.
  
- 2. Report on Nuclear Medicine Injection Extravasations as Medical Events** **M. Martin, ACMUI**  
Ms. Martin will discuss the ACMUI's draft subcommittee report on the NRC staff's draft proposed rule and associated draft implementation guidance for reporting nuclear medicine injection extravasations as medical events.
  
- 3. Closing and Adjournment** **H. Jadvar, ACMUI**  
Dr. Jadvar will close the meeting.