

MEETING OF THE
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

September 2, 2021

MEETING SUMMARY

PURPOSE

To discuss the ACMUI Subcommittee on Extravasation's review and comment on the U.S. Nuclear Regulatory Commission (NRC) staff's memorandum, "Preliminary Evaluation of Radiopharmaceutical Extravasation and Medical Event Reporting".

OUTCOME

The ACMUI Extravasation Subcommittee provided feedback and recommendations on the NRC staff's memorandum with the full ACMUI. Subcommittee members include: Dr. Vasken Dilsizian, Mr. Richard Green, Ms. Melissa Martin (chair), Mr. Michael Sheetz, and Ms. Megan Shober. The NRC staff resource is Lisa Dimmick. The NRC staff gained a better understanding of the views and opinions of the Committee. The NRC staff will consider the ACMUI's comments and recommendations on the preliminary evaluation of radiopharmaceutical extravasation and medical event reporting in its development of a SECY paper to be provided for Commission consideration.

Full transcripts and handouts from the ACMUI meeting can be found on the NRC's ACMUI Meetings and Related Documents webpage, located at: <https://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/2021.html>.

SUMMARY AND RECOMMENDATIONS

The U.S. NRC staff's memorandum was reviewed by the Extravasation Subcommittee and recommendations were presented to the full ACMUI. The Extravasation Subcommittee recommended changing the wording of option 4 of the Subcommittee report to read:

"Option 4 would be a non-dose-based option for reporting extravasations that result in a radiation injury. If a patient requires medical attention for a suspected radiation injury due to extravasation which results in tissue damage at or near the administration site, and this radiation injury is confirmed by a physician authorized user of the licensee to be due to radiation from the extravasation, then this will require medical event reporting."

With this amendment, the Subcommittee report was accepted unanimously and endorsed option 4 as modified.

The final report can be viewed, in its entirety, on the NRC's ACMUI Subcommittee Reports webpage, located at: <https://www.nrc.gov/reading-rm/doc-collections/acmui/reports/>.

MEETING ACTIONS

The following actions resulted from discussions that took place during the meeting:

Dr. Metter formed a new subcommittee, as detailed below:

1. Subcommittee on the Diffusing Alpha-emitter Radiation Therapy (DaRT) Manual Brachytherapy Source

Subcommittee Charge:

- To review and evaluate the staff's Alpha DaRT manual brachytherapy licensing guidance
- Provide considerations and recommendations to NRC staff

Subcommittee Membership: Dr. Ronald Ennis (chair), Mr. Zoubir Ouhib, Ms. Megan Shober, Dr. Michael O'Hara, Dr. Hossein Jadvar, Ms. Rebecca Allen

NRC Staff Resource: Dr. Katie Tapp

The subcommittee is expected to provide a draft report and any recommendations at the spring 2021 ACMUI meeting.

Enclosures:

1. Meeting Attendees
2. Meeting Agenda

MEETING PARTICIPANTS

ACMUI

Darlene F. Metter, M.D.	Chairman
A. Robert Schleipman, Ph.D.	Vice Chairman
Vasken Dilsizian, M.D.	Member
Ronald D. Ennis, M.D.	Member
Richard Green	Member
Hossein Jadvar, M.D.	Member
Josh Mailman	Member
Melissa Martin	Member
Michael D. O'Hara, Ph.D.	Member
Zoubir Ouhib	Member
Michael A. Sheetz	Member
Megan Shober	Member
Harvey B. Wolkov, M.D.	Member
John F. Angle, M.D.	(Consultant)

NRC STAFF

Chris Einberg	Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer
Maryann Ayoade	NMSS/MSST/MSEB
Said Daibes, Ph.D.	NMSS/MSST/MSEB
Daniel Dimarco	NMSS/MSST/MSEB
Lisa Dimmick	Medical Radiation Safety Team Leader, MSS/MSST/MSEB
Sarah Lopas	NMSS/MSST/MSEB
Lynn Ronewicz	NMSS/REFS/MRPB
Donna-Beth Howe, Ph.D.	NMSS/MSST/MSEB
Ian Irvin	OGC/GCLR/RMR
Katherine Tapp, Ph.D.	NMSS/MSST/MSEB

MEMBERS OF THE PUBLIC

Daniel Fass, M.D.,	Princeton Health Care Alliance
Miguel De La Guardia,	Cook Children's Medical Center
Ronald Lattanze,	Lucerno Dynamics
Ralph Lieto,	Michigan Radiological Society, American College of Radiology
Josh Knowland,	Lucerno Dynamics
David Townsend, Ph.D.,	Lucerno Dynamics
Matt Wait,	Kaiser Permanente
Paul Wallner, D.O.,	American College of Radiation Oncology
David Williams, M.D.,	Pediatrician

**Advisory Committee on the Medical Uses of Isotopes
TELECONFERENCE AGENDA
Thursday, September 2, 2021
1:00 PM – 3:00 PM EDT**

OPEN SESSION

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| 1. Opening Remarks | Mr. Chris Einberg will formally open the meeting. | C. Einberg, NRC |
| 2. Extravasations and Medical Event Reporting | Ms. Melissa Martin will present the ACMUI Subcommittee on Extravasations and Medical Event Reporting draft report on the NRC staff's preliminary evaluation on extravasations. | M. Martin, ACMUI |
| 3. Closing and Adjournment | Dr. Metter will close the meeting. | D. Metter, M.D.,
ACMUI |