

MEETING OF THE
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

December 15, 2021

MEETING SUMMARY

PURPOSE

To discuss (1) the Subcommittee on Alpha Dart 's review and comment on the U.S Nuclear Regulatory Commission (NRC) staff's draft Alpha Tau Alpha DaRT™ Manual Brachytherapy licensing guidance; (2) the Subcommittee on CivaDerm's review and comment on the NRC staff's memorandum, "Draft Licensing Guidance for Superficial Manual Brachytherapy CivaDerm Device"; and (3) the Subcommittee on Regulatory Guide 8.39's review and comment on the NRC staff's proposed revision 2 of Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material."

OUTCOME

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) subcommittees provided feedback and recommendations on the three documents developed by the NRC staff: draft Alpha Tau Alpha DaRT™ Manual Brachytherapy licensing guidance; NRC staff's memorandum, "Draft Licensing Guidance for Superficial Manual Brachytherapy CivaDerm Device"; and the proposed revision 2 of Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material." 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 prior to finalizing the three documents.

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

Subcommittee on Alpha Dart

Members: Dr. Ronald Ennis (chair), Dr. Hossein Jadvar, Dr. Michael O'Hara, Ms. Megan Shober, Ms. Becky Allen, Mr. Zoubir Ouhib, Dr. Katherine Tapp (NRC Staff Resource)

The Alpha Dart Subcommittee provided an overview and recommendations on the NRC staff's Alpha Tau Alpha DaRT™ Manual Brachytherapy licensing guidance. The Subcommittee discussed licensing of Alpha DaRT™ under 10 CFR 35.1000, roles of the authorized medical physicist and nuclear pharmacist, source leakage and integrity, contamination of procedure room, patient release, definition of medical event, and documentation of patient location.

The subcommittee report was unanimously approved by the ACMUI. The final report can be accessed at the ADAMS Accession No. ML22021B298.

Subcommittee on Regulatory Guide 8.39, Revision 2 (CivaDerm)

Members: Megan Shober (Chair), Dr. Vasken Dilsizian, Dr. Hossein Jadvar, Josh Mailman, Melissa Martin, Michael Sheetz (Consultant), Dr. Katherine Tapp (NRC Staff Resource)

The Subcommittee provided an overview and its recommendations on the NRC staff's memorandum, "Draft Licensing Guidance for Superficial Manual Brachytherapy CivaDerm Device." The Subcommittee recommended that CivaDerm should be licensed under 10 CFR 35.400 and recommended that the NRC staff develop a shorter guidance document that focuses on the consequences of loose or dislodged sources. Additionally, the Subcommittee believes it is unlikely that public dose limits will be exceeded if the Palladium-103 source is dislodged.

The subcommittee report was unanimously approved by the ACMUI. The final report can be accessed at the ADAMS Accession No. ML22021B299.

Subcommittee on Regulatory Guide 8.39, Revision 2

Members: Megan Shober (Chair), Dr. Vasken Dilsizian, Dr. Hossein Jadvar, Josh Mailman, Melissa Martin, Michael Sheetz (Consultant), Dr. Katherine Tapp (NRC Staff Resource)

The Subcommittee provided an overview and its recommendations on the NRC staff's proposed revision 2 to RG 8.39, "Release of Patients Administered Radioactive Materials." In Revision 2, the staff updated the dosimetric equations/methodologies used to calculate public dose from the released patient. Additionally, the staff made changes to the patient instructions and recommends analysis of public exposures from patient body cremation. The Subcommittee made six recommendations and provided specific comments on the NRC staff's draft RG 8.39. The recommendations were related to the patient instructions, occupancy factors, hold times, and calculation methodologies.

The subcommittee report was unanimously approved by the ACMUI. The final report can be accessed at the ADAMS Accession No. ML22021B300.

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

Enclosures:

1. Meeting Attendees
2. Meeting Agenda

MEETING PARTICIPANTS

ACMUI

Darlene F. Metter, M.D.	Chairman
Vasken Dilsizian, M.D.	Vice Chairman
Rebecca Allen	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
Megan Shober	Member
Harvey B. Wolkov, M.D.	Member

NRC STAFF

Chris Einberg	Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer
Maryann Ayoade	NMSS/MSST/MSEB
Angela Coggins	OGC/LHE/MFW
Daniel Dimarco	NMSS/MSST/MSEB
Robin Elliott	RI/DRSS/MLB
Cindy Flannery	NMSS/MSST/MSEB
Vincent Holahan	NMSS/MSST
Donna-Beth Howe, Ph.D.	NMSS/MSST/MSEB
Ian Irvin	OGC/GCRPS/RMR
Harriet Karagiannis	RES/DE/RGPMB
Erin Kennedy	RIII/DNMS/MLB
Penny Lanzisera	RI/DRSS/MLAB
Sarah Lopas	NMSS/MSST/MSEB
Don Lowman	NMSS/MSST/MSEB
Joan Olmstead	OGC/LRAA/RASFP
Vered Shaffer	RES/DSA/RPB
Michael Sheetz	ACMUI Consultant
Katherine Tapp, Ph.D.	NMSS/MSST/MSEB
Elizabeth Tindle-Engelman	RIII/DNMS/MIB
John Tomon	RES/DSA/RPB
Celimar Valentin-Rodriguez, Ph.D.	NMSS/MSST
Kevin Williams	NMSS/MSST

MEMBERS OF THE PUBLIC

Matthew Williamson
Ralph Lieto
Peter Crane
Dr. Michael Schuster
Jeffrey Brunette
Steven Frank – MD Anderson Cancer Center, Houston
Dr. Lisa Aldape – Seattle Children's Hospital
Dr. Firas Mourtada – Christian Care, Newark, DE
Mike Welling – University of Virginia

TELECONFERENCE MEETING AGENDA
Advisory Committee on The Medical Uses Of Isotopes

December 15, 2021
2:00 PM – 4:00 PM EST

OPEN SESSION

- 1. Opening Statements**
Mr. Chris Einberg will formally open the meeting. **C. Einberg, NRC**
- 2. Alpha Dart Licensing Guidance**
Dr. Ronald Ennis will present the ACMUI Subcommittee on Alpha Dart draft report on the NRC staff's draft licensing guidance. **R. Ennis, M.D.,
ACMUI**
- 3. CivaDerm**
Ms. Megan Shober will present the ACMUI Subcommittee on Civaderm draft report on the NRC staff's additional considerations memo for CivaDerm. **M. Shober, ACMUI**
- 4. Revision to Regulatory Guide 8.39**
Ms. Megan Shober will present the ACMUI Subcommittee on Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material" draft report on the NRC staff's draft revision of the regulatory guide. **M. Shober, ACMUI**
- 5. Closing and Adjournment**
Dr. Darlene Metter will close the meeting. **D. Metter, M.D.,
ACMUI**