TELECONFERENCE MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

February 15, 2018

MEETING SUMMARY

PURPOSE

To discuss the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Nursing Mothers' Guidelines Subcommittee's draft revised report on the recommendations on the cessation of breastfeeding for various radionuclides and the ACMUI Physical Presence Requirements for the Leksell Gamma Knife® Icon™ Subcommittee's draft revised report on the recommendations for the physical presence of authorized users (AUs) and authorized medical physicists (AMPs) during treatments using the Icon™ unit.

OUTCOME

The ACMUI Nursing Mothers' Guidelines Subcommittee provided a draft revised report for discussion with the full Committee. Subcommittee members included: Dr. Vasken Dilsizian, Dr. Darlene Metter (Chair), Dr. Christopher Palestro, and Dr. Pat Zanzonico. During the meeting, the Committee unanimously approved the revised draft report with the modifications outlined below. The final report will be submitted to the U.S. Nuclear Regulatory Commission (NRC) staff by the end of March 2018. The NRC staff gained a better understanding of the views and opinions of the Committee. The NRC staff will consider the Committee's recommendations 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.

The ACMUI Physical Presence Requirements for the Leksell Gamma Knife® Icon™ Subcommittee provided a draft revised report for discussion with the full Committee. Subcommittee members included: Dr. Ronald Ennis, Dr. John Suh (Chair), and Ms. Laura Weil. During the meeting, the Committee unanimously approved the draft revised report. The final report was submitted to the NRC staff on February 27, 2018. The NRC staff will consider the Committee's recommendations for possible amendments to the 10 CFR 35.1000 Licensing Guidance for the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™.

A full transcript and handout for the ACMUI teleconference meeting can be found on NRC's public website at: http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/.

The draft and final ACMUI Subcommittee reports are available on NRC's public website under "ACMUI Subcommittee Reports": http://www.nrc.gov/reading-rm/doc-collections/acmui/reports/.

AGENDA TOPIC

1. Discuss the Revised Draft Report of the ACMUI Nursing Mother Guidelines for the Medical Administration of Radioactive Materials.

2. Discuss the Revised Draft Report of the ACMUI Physical Presence Requirements for the Leksell Gamma Knife® Icon™.

SUMMARY

The ACMUI Nursing Mothers' Guidelines Subcommittee reviewed the radiation exposure from diagnostic and therapeutic radiopharmaceuticals, including brachytherapy, to the nursing mother and child. The Subcommittee recommended interruption periods for breast-feeding and for the close physical proximity of the nursing mother to the nursing child (i.e., caressing or holding the child with a similar distance to the mother as for breast-feeding).

The ACMUI Physical Presence Requirements for the Leksell Gamma Knife® Icon™ Subcommittee reviewed and evaluated the existing physical presence requirements for Icon™ unit AUs. The Subcommittee recommended modifying the requirements such that AUs will be physically present (within hearing distance) at the initiation of treatment, but are able to be within a two minute walking distance to the Icon™ console area **and** immediately available to come to the treatment room. The AU will return to the console should there be any re-initiations and at the conclusion of the treatment to discuss any treatment or patient issues with the patient, physicist, and nurse. These recommendations are for the Icon™ unit, in either the stereotactic frame or frameless mask mode.

RECOMMENDATIONS AND ACTIONS

The Nursing Mothers' Guidelines Subcommittee discussed the following recommendations in the revised draft subcommittee report:

1. *For technetium-99m (^{99m}Tc)-labeled radiopharmaceuticals, rather than a radiopharmaceutical-specific interruption period, a single interruption period of 24-hours is recommended. Although this time interval may be longer than absolutely necessary for some ^{99m}Tc-labeled radiopharmaceuticals, it is compliant with the 100-mrem dose limit and simplifies the guidance, thereby avoiding confusion and reducing the likelihood of error.*

2. *For flourine-18(^{18}F)-fludeoxyglucose[1], all other ^{18}F-labeled and all gallium-68 (^{68}Ga)-labeled radiopharmaceuticals, a 12-hour interruption period is recommended. This conservative recommendation is cautious and simplifies safety instructions for patients and medical professionals. A 12-hour interruption period is recommended for ^{68}Ga for the following reasons: (a) a physical half-life comparable to that of ^{18}F, (b) the propensity of free radiogallium to accumulate in breast milk and (c) the lack of relevant data on ^{68}Ga-labeled agents in nursing mothers.*

3. *For very-short-lived positron-emitting radionuclides used in imaging, carbon-11 (^{11}C) (physical half-life: 20.4 min), nitrogen-13 (^{13}N) (9.97 min), oxygen-15 (^{15}O) (2.04 min), and generator-produced rubidium-82 (^{82}Rb) (1.27 min), no interruption in breast-feeding is recommended, since there is no significant activity remaining in the mother after the procedure is completed.*

4. *For iodine-123 (^{123}I) in the form of sodium-iodide (NaI) (^{123}I-NaI), an interruption period of 7 days is recommended. This is in marked contrast to the past, where complete cessation of breast-feeding for the current child was recommended. This older, more stringent ^{123}I-NaI recommendation was largely based on contamination (up to 2.5% of*

[1] Fludeoxyglucose is commonly referred to as FDG.

the total activity) with long-lived iodine-125 (^{125}I) (physical half-life: 60 days) that occurred with older methods of ^{123}I production. Such contamination of ^{123}I with ^{125}I no longer occurs. Therefore, the restrictions on breast-feeding following ^{123}I-NaI administration to the nursing mother may be justifiably relaxed to an interruption period of 7 days.

5. *For gallium-67 (^{67}Ga)-gallium-citrate, an interruption period of 28 days is recommended, which is consistent with the most conservative recommendations for ^{67}Ga in the literature. For indium-111 (^{111}In) labeled white cells an interruption period of 7 days and for thallium-201 (^{201}Tl-chloride) an interruption period of 14 days are recommended. These recommendations mirror that of the NRC in the Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, NUREG-1556, Vol 9, Rev 2, Appendix U, 2008.*

6. *For zirconium-89 (^{89}Zr), a 28-day (i.e., 4-week) interruption period was set equal to the maximum recommended interruption period for ^{67}Ga. The rationale for this recommendation are the comparable physical half-lives of ^{89}Zr (3.27 days) and ^{67}Ga (3.26 days). Both ^{89}Zr and ^{67}Ga are radiometals and may share some common chemical properties, and lastly, there is a lack of relevant data on ^{89}Zr-labeled agents in nursing mothers.*

   For lutecium-177 (^{177}Lu), based on the foregoing ^{89}Zr rationale and a longer physical half-life (6.65 days), an interruption period of 35-days (i.e., 5 weeks) is recommended for ^{177}Lu-labeled radiopharmaceuticals used diagnostically. For ^{177}Lu-labeled radiopharmaceuticals used therapeutically, much higher activities are administered, and thus, permanent cessation of breast-feeding for the current child is recommended.

7. *For radium-223 (^{223}Ra) and all other alpha particle-emitting radionuclides, permanent discontinuation of breast-feeding for the current child is recommended. Alpha particles are densely ionizing, have high-linear energy transfer radiations that potentially incur far more significant biological effects than beta-particles, and are of particular concern in the young child in whom rapid growth and development are occurring. In the absence of relevant data and out of an abundance of caution, permanent discontinuation of breast-feeding for the current child is therefore recommended.*

The Revised Draft Nursing Mother Guidelines for the Medical Administration of Radioactive Materials Subcommittee Report (ML18033B034) was unanimously approved by the full ACMUI with modifications to: (1) include recommended cessation periods for both 100 and 500 mrem limits; (2) acknowledge benefits of breastfeeding; (3) incorporate corrections as needed for gamma ray constants; (4) convert the units from conventional to SI units; and (5) correct references. The final report will be posted the ACMUI Subcommittee Reports Webpage by April 2018.

The Physical Presence Requirements for the Leksell Gamma Knife® Icon™ Subcommittee discussed the following recommendations in the revised draft subcommittee report:

8. *The AU and AMP should be physically present during the initiation of all treatments involving the Icon™ unit.*

9. *The current physical presence requirements for the AU can be modified by allowing the AU to be close enough to the console to respond quickly to any issue that arises, which is defined as within a two minute walking distance to the Icon™ console area,* ***and*** *immediately available to come to the treatment room. An AMP needs to be physically present during the entire treatment.*

   In addition to the AU and AMP, as a matter of good practice, we recommend that appropriately trained nursing or auxiliary staff be present during Icon™ treatment to respond to any immediate medical needs. It will be the responsibility of the AU to determine the necessary training and experience required of the nursing staff, who will be present throughout the procedure.

10. *If there is an interruption of treatment secondary to medical or mechanical issues, the AU must return to the Gamma Knife® Icon™ console to evaluate the patient and/or to review any mechanical issues. The AU must be present to ensure that the correct site is being treated during re-initiation of treatment.*

11. *At the conclusion of treatment, the AU must be present at the Icon™ console to discuss any treatment or patient issues with the patient, physicist, and nurse.*

The Revised Draft Physical Presence Requirements for the Leksell Gamma Knife® Icon™ Subcommittee Report (ML18033B033) was unanimously approved by the full ACMUI. The Final Physical Presence Requirements for the Leksell Gamma Knife® Icon™ Report (ML18071A413) is posted on the ACMUI Subcommittee Reports Webpage.

Attachments:

1. List of Attendees
2. Agenda

MEETING ATTENDEES

ACMUI

Philip O. Alderson, M.D.	Chairman
Pat B. Zanzonico, Ph.D.	Vice Chairman
Vasken Dilsizian, M.D.	Member
Ronald D. Ennis, M.D.	Member
Darlene F. Metter, M.D.	Member
Michael D. O'Hara, Ph.D.	Member
Christopher J. Palestro, M.D.	Member
Michael Sheetz	Member
John H. Suh, M.D.	Member
Laura M. Weil	Member
Richard Green	Non-Voting Member
Zoubir Ouhib	Non-Voting Member
Megan Shober	Non-Voting Member

NRC

Christian Einberg	Acting, Deputy Director, Division of Material Safety, Security, State, and Tribal Programs (MSST)
Douglas Bollock	Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer
Sophie Holiday	Alternate Designated Federal Officer/ACMUI Coordinator
Maryann Ayoade	NMSS/MSST
Jennifer Bishop	RIII
Said Daibes, Ph.D.	NMSS/MSST
Jason Draper	RIII
Sara Forster	RIII
Cassandra Frazier	RIII
Michelle Hammond	RIV
Vincent Holahan, Ph.D.	NMSS/MSST
Patricia Jehle	OGC
Jan Nguyen	RI
Patty Pelke	RIII
Gretchen Rivera-Capella	NMSS/MSST
Vered Shaffer	RES
Laura Shrum	OGC
Daniel Strohmeyer	RIII
Katherine Tapp, Ph.D.	NMSS/MSST
Frank Tran	RIII
Lester Tripp	RI
Irene Wu	NMSS/MSST

MEMBERS OF THE PUBLIC

Bette Blankenship	American Association of Physicists in Medicine (AAPM)
Kelly Classic	Mayo Clinic
Charles Codleman	VA Radioactive Materials Program

Thomas Conley	University of Kansas Medical Center
Whitney Cox	Illinois (IL) Emergency Management Agency
Robert Dansereau	New York State (NYS) Department of Health
Ariel Doucet	Virtua Health
Adam Ekstedt	IL Emergency Management Agency
Asfaw Fenta	Virginia (VA) Radioactive Materials Program
Michael Fuller	VA Radioactive Materials Program
Miguel de la Guardia	Cook Children's Health Care System
Sandra Gabriel	*unaffiliated*
Jerry George	Baptist Health South Florida
Kimberly Gilliam	VA Radioactive Materials Program
Theodore Godfrey	Elekta, Inc.
Bennett Greenspan	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Stanley Hampton	Eli Lilly and Company
Steve Harrison	VA Radioactive Materials Program
Desiree Kennedy	Elekta, Inc.
Richard Kenney	*unaffiliated*
Tim Kleyn	Indiana University
Janaki Krishnamoothy	NYS Department of Health
Susan Lohman	Elekta, Inc.
Lanchu Lu	Ohio State University Medical Center
Carol Marcus	University of California at Los Angeles
Richard Martin	American Association of Physicists in Medicine (AAPM)
Barbara Matthews	Baptist Memorial Health Care Corporation
Catherine Perham	Maine Radiation Control Program
Richard Peros	New Jersey Radioactive Materials Program
Eric Perry	Kentucky Radioactive Materials Section
Michael Peters	American College of Radiology (ACR)
Bruce Proctor	Elekta.Inc.
Brad Read	Elekta, Inc.
Slyvia Revell	University of Texas Southwestern Medical School
Daniel Samson	NYS Department of Health
Beth Schilke	VA Radioactive Materials Program
A. Robert Schleipman	Partners Healthcare
Lou Shimabuku	*unaffiliated*
Eugenio Silverstrini	Northwell Health
Michael Stabin	Vanderbilt University
Cindy Tomlinson	American Society of Radiation Oncology (ASTRO)
Michael Welling	University of Virginia

Advisory Committee on the Medical Uses of Isotopes
TELECONFERENCE AGENDA
Thursday, February 15, 2018
9:00 AM – 11:00 AM (ET)

OPEN SESSION

9:00 – 10:00 am
Discuss the Revised Draft Report of the ACMUI Nursing Mother Guidelines for the Medical Administration of Radioactive Materials

10:00 – 11:00 am
Discuss the Revised Draft Report of the ACMUI Physical Presence Requirements for the Leksell Gamma Knife® Icon™