MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
September 20–21, 2018
One White Flint North Building (Commission Hearing Room), Rockville, Maryland

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.

	Thursday, September 20, 2018 **CLOSED SESSION**	
7:30 – 10:30	• **Badging and Enrollment** • **INFOSEC Training** • **Ethics Training** • **Allegations Training**	**PERSEC, NRC** **R. Norman, NRC** **J. Suttenberg & J. Ezell, NRC** **D. Willis, NRC**
10:30 – 11:00	**BREAK**	
	OPEN SESSION	
11:00 – 11:45	• **Opening Remarks** Mr. Bollock will formally open the meeting and Ms. Atack will provide opening comments.	**D. Bollock & S. Atack, NRC**
	• **Old Business** Ms. Dimmick will review past ACMUI recommendations and provide NRC responses.	**L. Dimmick, NRC**
	• **Open Forum** The ACMUI will identify medical topics of interest for further discussion.	**ACMUI**
11:45 – 12:45	**LUNCH**	
12:45 – 2:30	• **Medical Events Subcommittee Report** Dr. Ennis will present the subcommittee's analysis of medical events for fiscal year 2017.	**R. Ennis, ACMUI**
	• **Non-Medical Events** Mr. Sheetz will did non-medical events reported by medical use facilities and commercial pharmacies.	**M. Sheetz, ACMUI**
	• **ABS Medical Event Case Study Program** Mr. Ouhib will discuss the American Brachytherapy Society's effort to reach out to the brachytherapy community for creative corrective actions regarding events that have taken place.	**Z. Ouhib, ACMUI**
2:30 – 2:45	**BREAK**	

	• **T&E for All Modalities Subcommittee Update** Dr. Metter will provide an update on the actions of the training and experience for all modalities subcommittee and the planned path forward.	**D. Metter, ACMUI**
	• **T&E Stakeholder Outreach Plan** Ms. Ayoade will present the staff's outreach plan for the continued evaluation of training and experience.	**M. Ayoade, NRC**
2:45 – 5:00	• **ACMUI-SNMMI Session at the 2018 SNMMI Annual Meeting** Dr. Palestro will provide an overview of the topics discussed by ACMUI at the 2018 SNNMI meeting in Philadelphia, PA.	**C. Palestro, ACMUI**
	• **Nursing Mother Guidelines Subcommittee Report** Dr. Metter will discuss the subcommittee's final report on the nursing mother guidelines for exposure from diagnostic and therapeutic radiopharmaceuticals.	**D. Metter, ACMUI**
	• **ACMUI Comments on the Draft Revision of the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance** Dr. Suh will discuss the subcommittee's comments on the draft revision of the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ licensing guidance.	**J. Suh, ACMUI**

Friday, September 21, 2018
OPEN SESSION

	• **Special Presentation to Dr. Suh** Mr. Dapas will make a special presentation to Dr. Suh.	**M. Dapas, NRC**
	• **Dr. Suh's Thoughts on Leaving ACMUI** Dr. Suh will share his thoughts on leaving the ACMUI.	**J. Suh, ACMUI**
8:30 – 10:15	• **Special Presentation to Dr. Alderson** Mr. Dapas will make a presentation to Dr. Alderson.	**M. Dapas, NRC**
	• **Dr. Alderson's Thoughts on Leaving ACMUI** Dr. Alderson will share his thoughts on leaving the ACMUI.	**P. Alderson, ACMUI**
	• **Y-90 Microspheres Brachytherapy Licensing Guidance** Dr. Tapp will discuss the current status of the yttrium-90 working group's revised guidance and planned actions.	**K. Tapp, NRC**
10:15 – 10:45	**BREAK**	
10:45 – 11:15	• **Compounding of Sterile and Non-Sterile Radiopharmaceuticals** Mr. Green will discuss the establishment of an Expert Panel by USP to develop USP Standards of sterile and non-sterile radiopharmaceutical preparation.	**R. Green, ACMUI**

	• **Medical Team Highlights** Ms. Dimmick will recap the work of the Medical Radiation Safety Team for fiscal year 2018.	**L. Dimmick, NRC**
11:15 – 12:00	• **Open Forum** The ACMUI will discuss medical topics of interest previous identified.	**ACMUI**
12:00 – 1:00	**LUNCH**	
	• **ACMUI, Subcommittees, NRC staff, NRC management: How the Team Works Under FACA** Mr. Chazell and Mr. Bollock will discuss the roles and responsibilities of each under the Federal Advisory Committee Act (FACA).	**R. Chazell & D. Bollock, NRC**
1:00 – 3:00	• **ACMUI Subcommittees, Subcommittee Membership, and the ACMUI Chair** Dr. Palestro will discuss the possible need for ACMUI bylaw changes and the need to update subcommittee membership, form new subcommittees and sunset other subcommittees.	**C. Palestro, ACMUI**
	• **Administrative Closing** Ms. Dimmick will provide a meeting summary and propose dates for the spring 2019 meeting.	**L. Dimmick, NRC**
3:00	**ADJOURN**	

Opening Remarks

NO HANDOUT

Fall 2018 Old Business

2007 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
33	NRC staff should modify 10 CFR 35.491(b)(2) to specify 'superficial' ophthalmic treatments. Additionally, NRC staff should change the title of 10 CFR 35.491 to specify 'superficial' ophthalmic treatments.	10/22/07	Accepted	Open *Delayed*
34	NRC staff should not revise 10 CFR 35.491 (intended for ophthalmologists) to include training and experience for the new intraocular device. Instead, NRC staff should regulate the new intraocular device under 10 CFR 35.490.	10/22/07	Partially Accepted	Open *Delayed*

	ITEM	DATE	STATUS	
19	NRC staff should accept the six recommendations of the Permanent Implant Brachytherapy Subcommittee report with one modification. Recommendation six should be modified to read, "When a Written Directive (WD) is required, administrations without a prior WD are to be reported as regulatory violations and may or may not constitute an ME."	10/27/08	Pending	Open *Delayed*
26	NRC staff should revise 10 CFR 35.40 to clarify that the AU should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs	10/28/08	Accepted	Open *Delayed*

	ITEM	DATE	STATUS	
16	Dr. Alderson formed a subcommittee to review and evaluate the training and experience requirements for all modalities in 10 CFR Part 35. Subcommittee members include: Dr. Langhorst, Dr. Metter, Dr. Palestro (chair), Dr. Suh and Ms. Weil. NRC staff resource: Maryann Abogunde.	2/25/2016	ACMUI Action	Open Indefinitely
24	The ACMUI will contact their respective professional organizations to request and encourage interactions between the NRC and ACMUI with their organization.	3/18/2016	ACMUI Action	Open Indefinitely
39	The Committee recommended that staff issue a generic communication (information notice) regarding tubing issues (kinking, connection, hub etc.) during the administration of Y-90 microspheres brachytherapy.	10/6/16	NRC Action	Open
42	The Committee recommended that the Pathway 2 remain for the Y-90 Microsphere Brachytherapy Licensing Guidance. The NRC/OAS working group should determine what the requirements should be for the proctoring of cases by the manufacturer(s).	10/7/16	NRC Action	Open
43	The Committee recommended to support the update to the waste disposal section and the review of the Y-90 radiation safety issues in autopsy and cremation in the draft revision of the Y-90 Microsphere Brachytherapy Licensing Guidance.	10/7/16	NRC Action	Open
49	For the NorthStar Guidance Subcommittee: The Committee recommended that the guidance clarify whether the generator will be “non-operational” until ALL individuals handling the generator are trained in the changes, including the AU, RSO, system administrator, etc. or does it require only the AU to be trained on the “changes.” If the latter, once the AU is trained on the “changes”, is the AU then solely responsible for training all others on these changes? This should be stated.	10/7/16	NRC Action	Open
50	For the NorthStar Guidance Subcommittee: The Committee recommended using the term, “individual tasks” throughout the document for consistency and to clarify that there is only one protocol and software program with this system.	10/7/16	NRC Action	Open

	ITEM	DATE	STATUS	
51	For the NorthStar Guidance Subcommittee: The Committee recommended that the manufacturer's procedures be reviewed and incorporated into the Licensing Guidance itself.	10/7/16	NRC Action	Open
52	For the NorthStar Guidance Subcommittee: The Committee recommended that the term "higher than expected" be defined in terms of a maximum specific exposure or exposure-rate limit which a survey meter should be capable of measuring.	10/7/16	NRC Action	Open
53	The Committee endorsed the NorthStar Mo-99/Tc-99m Generator (RadioGenix) Subcommittee Report.	10/7/16	ACMUI Action	Open

2017 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
1	The Committee requested that the recommendations and actions pertaining to the Part 35 rulemaking be reviewed during the fall 2017 ACMUI neeting and that additional time be provided to review each item.	4/26/2017	NRC Action	*Pending*
12	The NRC staff will engage in discussions with the OAS to find a way to centralize event reporting from the Agreement States.	9/11/2017	NRC Action	Open
13	The ACMUI recommended that the NRC establish a program allowing a medical use licensee to evaluate MEs as described in 10 CFR 35.3045, in NRC 10 CFR 35.1000 licensing guidance, and in 10 CFR 35.3047 with an approved patient safety program.	9/11/2017	NRC Action	Open

14	The ACMUI recommended that NRC licensees with an NRC-approved patient safety program will continue to report medical events as required with the following conditions: (1) The NRC will not include this event notification in the Event Notification Report posted on its website. If this is not possible, the ME notification posted on the website will leave the licensee information and location anonymous. (2) The NRC will not conduct a reactive inspection of the ME unless the event results or will result in death, unintended permanent harm, or unintended significant temporary harm for which medical intervention was or will be required to alleviate the harm or reduce radiation effects. (3) The medical use licensee will write a report available for the next NRC inspection describing the event cause and corrective action taken. (4) NRC will develop, with ACMUI advice, new temporary inspection procedures for NRC review of licensee patient safety event reports, and will evaluate, with ACMUI advice, need to change enforcement manual procedures regarding MEs to support a test of this program.	9/11/2017	NRC Action	Open

15	The ACMUI recommended that NRC should test out this program with two large medical centers, two community hospitals, two rural hospitals, and two patient clinics for a year, evaluating the ME reports with the ACMUI. During this test period, the NRC, with advice from the ACMUI, should do the following: (1) Develop the minimum criteria for patient safety program reviews; (2) Assess how this change in ME reporting impacts the NRC's ability to protect patient health and to minimize danger to the patient's life; and (3) Evaluate the different types of patient safety programs in how lessons learned from their patient safety incident reviews are shared with the medical community.	9/11/2017	NRC Action	Open
16	The ACMUI recommended that after completion of the test year, the NRC should consider opening the program to all NRC medical use licensees who request approval of their patient safety program, and to Agreement States who request to implement the program with their medical licensees.	9/11/2017	NRC Action	Open
17	The ACMUI recommended that the NRC redefine its perspective of patient safety to be different from occupational safety and from public safety.	9/11/2017	NRC Action	Open
18	The ACMUI recommended that NRC partner with the Department of Health and Human Services (HHS), specially the Agency for Healthcare and Research and Quality (AHRQ) , and ACMUI to develop a national database taxonomy specific for reporting patient events involving medical use of byproduct material.	9/11/2017	NRC Action	Open

19	The ACMUI recommended that the NRC Update its Medical Use Policy Statement and 10 CFR 35 event reporting regulations for patient safety programs to verify the active involvement of the licensee's patient safety program review of medical errors and reporting of reviews to the national patient safety database.	9/11/2017	NRC Action	Open
20	The ACMUI endorsed the Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture Draft Report, as amended to support the concept of the pilot program with the total number of sites and duration to be determined at a later date and to include the Patient Intervention Subcommittee recommendations as an addendum .	9/11/2017	ACMUI Action	Open

2018 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
1	The ACMUI recommended that there be no breast feeding cessation for ^{11}C, ^{13}N, ^{15}O, and ^{82}Rb; a 12-hours cessation for ^{18}F-labeled and 68Ga-labeled; a 24-hours cessation for ^{99m}Tc-labeled; 7-days cessation for ^{123}I-NaI and ^{111}In-leukocytes; 14 days cessation for $^{201-}$Tl-chloride; 28 days cessation for ^{67}Ga and ^{89}Zr; 35 days for ^{177}Lu, diagnostic; and total stop of breastfeeding for ^{131}I-NaI, ^{177}Lu, therapeutic, ^{223}Ra and all alpha emitters.	2/15/2018	NRC Action	Open
2	The ACMUI endorsed the Nursing Mother Guidelines for the Medical Administration of Radioactive Materials Subcommittee Report, as amended 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.	2/15/2018	ACMUI Action	Open
3	The ACMUI recommended that the AU be physically present during the initiation of all Leksell Gamma Knife Icon treatments. However, the AU could be present in the department (defined as a two minute walk to the console area) during treatment but is immediately available to come to the treatment room. If there is an interruption of treatment secondary to medical or mechanical issues, the AU must return to the console prior to reinitiation.	2/15/2018	NRC Action	Open

4	The ACMUI recommended as a best practice that appropriately trained nursing or auxiliary staff be present at the console to respond to any immediate medical needs.	2/15/2018	ACMUI Action	Open
5	The ACMUI unanimously endorsed the Physical Presence Requirements for the Leksell Gamma Knife Icon Subcommittee Report.	2/15/2018	ACMUI Action	Open
6	The NRC staff will create an ACMUI Recommendations Web page and post the full ACMUI Recommendations and Actions charts on the ACMUI Web page from 2007 – present	3/7/2018	NRC Action	Open Indefinitely
7	The NRC staff will send out a medical list server announcement to inform subscribers of the availability of ACMUI and NRC ME slides each time that they are posted on the Medical Toolkit.	3/7/2018	NRC Action	Open Indefinitely
8	The ACMUI tentatively planned to hold its Fall 2018 Meeting on September 20-21, 2018. The back-up dates are September 17-18, 2018.	3/8/2018	ACMUI Action	Open
9	Dr. Palestro appointed Ms. Megan Shober and Mr. Zoubir Ouhib to the Physical Presence Requirements for the Leksell Gamma Knife Icon Subcommittee. Subcommittee membership includes: Dr. Ennis, Mr. Ouhib, Ms. Shober, Dr. Suh (Chair), and Ms. Weil. NRC POC: Sophie Holiday	7/16/2018	ACMUI Action	Open
10	The ACMUI endorsed the T&E SECY Paper Subcommittee Report.	7/16/2018	ACMUI Action	Open

Open Forum

NO HANDOUT

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Medical Events Subcommittee Report

Ronald D. Ennis, M.D.

Advisory Committee for the Medical Uses of Isotopes

September 20, 2018

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Subcommittee Members

- Ronald D. Ennis, M.D. (Chair)
- Richard Green
- Darlene Metter, M.D.
- Michael O'Hara, Ph.D.
- John Suh, M.D.
- Michael Sheetz

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Process

- This year, rather than review the details of specific cases, we are reporting on our overview of events over last 3.5 years to discern common themes within each section of 10 CFR Part 35 and across the sections, to inform a discussion of possible ways to decrease medical events (MEs).
- We reviewed the last three reports of this subcommittee (FYs 2014-16) as well as the spring report of Dr. Howe for FY 2017

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Summary

- Two overarching themes emerged
  - Performance of a time out immediately prior to administration of radioactive byproduct material, as is done in surgery and other settings, could have prevented some MEs
  - Lack of recent or frequent performance of the specific administration appears to be a contributing factor in a number of cases

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35.200 Use of Unsealed Byproduct Material for Imaging and Localization

Medical Events Summary

	2014	2015	2016	2017	Total
Cause					
Wrong drug*	0	3	3	0	6
Wrong dosage	5	0	3	3	11
Wrong patient	1	1	2	0	4
Total	6	4	8	3	21

* In most cases wrong drug was also wrong dosage

21 events over 4 years

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35.200 Use of Unsealed Byproduct Material for Imaging and Localization

How Can These Events Be Prevented?

- Wrong drug: Time out - confirm the order, compare to the prescription
- Wrong dosage: If a dose calibrator is available – measure the activity
- Wrong patient: Time out - Verify patients by two means of identification
- 10/21 preventable if time out had been used

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35.300 Use of Unsealed Byproduct Material, Written Directive Required

Medical Event Summary

	2014	2015	2016	2017	Total
WD not done or incorrectly	0	1	0	2	3
Error in delivery (#capsules)	2	3	1	1	7
Wrong dose	0	2	3	0	5
Equipment	1	1	0	0	2
Unauthorized clinic	0	0	1	0	1
Wrong patient	1	0	0	1	2
Total	4	7	5	4	20

Time out could prevent 10-17/20

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35.400 Manual Brachytherapy

Medical Event Summary

	2014	2015	2016	2017	Total
Applicator issue (e.g. movement during implant	1	1	1	0	3
Wrong site implanted (e.g. penile bulb)	3	1	1	1	6
Activity/prescription error (e.g. air kerma vs mCi)	1	2	0	1	4
Prostate Dose	0	4	18	5	27

35.400 Manual Brachytherapy

Medical Event Summary

	2014	2015	2016	2018	Total
Total ME	5	8	20	7	40
"Time out" may have prevented	1	2	0	1	4 (10%)
Lack of experience may have played a role	3	1	1	1	6 (15%)

35.400 Manual Brachytherapy

Many MEs in this category are no longer categorized as MEs due to change from dose- to activity-based definition.

Lack of experience possibly plays a role in the true MEs of this type, but hard to assess to what degree in each case.

In approximately 25% of cases, a "time out" or enhanced retraining prior to performance of an uncommon procedure might have prevented the ME.

35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic unit

Medical Event Summary

	2014	2015	2016	2017
Cause				
Wrong position	3	6	1	2
Wrong reference length	2	3	0	2
Wrong plan	1	3	1	0
Wrong dose/source strength	2	0	0	0
Machine malfunction	2	2	3	2
Software failure	0	0	0	2 (9 pts)
Total	10	14	5	8 (14 pts)

37 events over 4 years

35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic unit

Medical Event Summary

	2014	2015	2016	2017
Location				
Breast	1	1	0	0
Gynecological	5	9	2	7 (14 pts)
Skin	2	1	1	0
Bronchus	1	2	0	0
Prostate	0	0	2	0
Brain	1	1	0	1
Total	10	14	5	8 (14 pts)

GYN tumors most common site of ME

35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic unit

MEs that may have been prevented by "timeout" (wrong plans or dose)

- 2014 3/10 events
- 2015 3/14 events
- 2016 1/5 events
- 2017 0/8 events

Total 6/37 (16.2%)

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35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic unit

MEs caused by "infrequent user"

This is difficult to determine based on information on NMED. If assumption is made about wrong position as surrogate for "infrequent" user

- 2014 3/10 events
- 2015 6/14 events
- 2016 1/5 events
- 2017 2/8 events

Total 12/37 (32.4%)

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35.1000 Radioactive Seed Localization

Medical Events Summary

	2014	2015	2016	2017
Total Medical Events	1	1	0	2
Cause:				
Delayed seed removal (patient intervention)	1	1		
Lost seed				1
Wrong implant site				1

35.1000 Gamma Knife® Perfexion™ and Icon™

Medical Events Summary

	2014	2015	2016	2017
Total Medical Events	1	8	3	0
Cause:				
Patient positioning system misalignment by vendor (same site)		8		
Patient setup error			2	
Patient movement			1	
Wrong site (treatment plan)	1			

35.1000 Y-90 Therasphere

Medical Events Summary

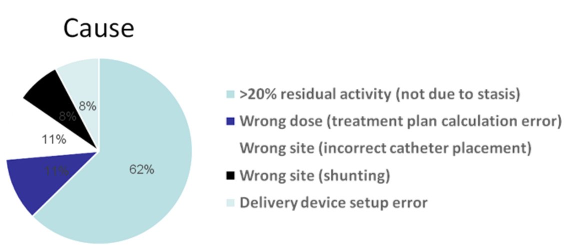
	2014	2015	2016	2017
Total Medical Events	9	8	13	15
Cause:				
> 20% residual activity remaining in delivery device	6	7	9	7
Delivery device setup error			1	2
Wrong dose (treatment plan calculation error)	1		1	4
Wrong site (catheter placement error)	1	1	2	2
Wrong site (shunting)	1			

35.1000 Y-90 SirSpheres

Medical Events Summary

	2014	2015	2016	2017
Total Medical Events	15	10	13	8
Cause:				
> 20% residual activity remaining in delivery device not due to stasis	10	2	9	7
Wrong site (shunting)	2	4		
Delivery device setup error	1	3		
Wrong dose (treatment plan calculation error)	1	1	2	
Wrong site (catheter placement error)	1		2	1

Overview Y-90 Microsphere ME 2014 - 2017



Actions to Prevent 35.1000 Y-90 Microsphere Medical Events

- Review mechanics of Y-90 microsphere delivery device and setup procedures
- Confirm all data and calculations in treatment plan
- Perform "Time Out" to assure all elements of treatment are in accordance with Written Directive

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35.1000 Medical Events That May Have Been Prevented by "Time Out"

	RSL	Perfexion/Icon	Y-90 Microspheres
2014	1/2	1/1	3/24
2015	0/1	0/8	2/18
2016	0/1	2/3	3/26
2017	0	0	3/23
Total	1/4 (25%)	3/12 (25%)	11/91 (12%)

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35.1000 Medical Events That May Have Been Attributed to Lack of Experience or Infrequent User

	RSL	Perfexion/Icon	Y-90 Microspheres
2014	0/2	0/1	1/24
2015	0/1	0/8	3/18
2016	0/1	2/3	1/26
2017	0	0	2/23
Total	0/4 (0%)	2/12 (17%)	7/91 (8%)

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Possible Elements of a "Time Out"

- Identity of patient via two identifiers (e.g. name and DOB)
- Procedure to be performed
- Isotope
- Activity
- Dosage
- Others as applicable
  - units of activity (LDR prostate)
  - anatomic location
  - patient name on treatment plan
  - treatment plan independent second check has been performed
  - reference length (HDR)
  - Implant site location (RSL)

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Possible Elements of Refresher for Infrequent Procedure

- Take review course from professional society
- Read review articles
- Speak to colleague with experience
- Do dry run of procedure with the team
- Review mechanics of device set up and procedure

Recommendation for Action

The subcommittee recommends the NRC issue an Information Notice alerting AUs to the themes identified herein

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Acronyms

- 10 CFR – Title 10 of the *Code of Federal Regulations*
- AUs – authorized users
- DOB – date of birth
- FY – Fiscal Year
- Gy – Gray
- gyn – gynecological
- HDR – high dose-rate

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Acronyms

- LDR – low dose rate
- mCi – milliCurie
- ME – Medical Event
- RSL – radioactive seed localization
- Y – Yttrium

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Non-Medical Byproduct Material Events FY 17

Michael Sheetz
Advisory Committee for the Medical Use of Isotopes
September 20, 2018

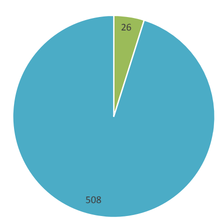
Non-Medical Events

- NMED event involving medical licensee
- Does not include medical events under 10 CFR 35.3045 or 35.3047, or other patient safety events
- Includes events reported under:
  - 10 CFR 35.3067 (leaking source)
  - 10 CFR 20.2201 (lost or stolen material)
  - 10 CFR 20.2202 (over exposures)
  - 10 CFR 30.50 (contamination)
  - 49 CFR 171.15 (transportation incidents)

Non-Medical Event Categories
Identified in FY17

- Leaking Source – 8
- Lost, Abandoned, or Stolen Sources – 7
- Overexposure – 4
- Shipment of Radioactive Material – 4
- Radioactive Contamination – 3
- Equipment Malfunction – 0

Total NMED Events (All Categories)
FY 17



■ Non-Medical Events from Medical Licensees

■ All Other Events

Non-Medical Event
Lost, Abandoned, or Stolen Sources
FY17

- Lost I-125 RSL seed - 3
- Lost Cs-137 dose calibrator vial source - 2
- Missing I-125 brachytherapy seeds - 1
- Loss and recovery Ir-192 HDR source - 1

Non-Medical Event
Leaking Sealed Source
FY17

- Cs-137 dose calibrator vial - 5
- Ir-192 HDR - 1
- I-125 RSL cut seed - 1
- P-32 flex brachytherapy film - 1

Non-Medical Event
Shipment of Radioactive Material
FY17

- Contaminated package - 3
- Damaged package - 1

Non-Medical Event
Radioactive Contamination
FY17

- Contamination of hospital room from patient with previous I-131 therapy - 1
- Contamination of nuclear medicine room from child administered I-131 capsule - 1
- Contamination of IR suite from improper setup of Y-90 microsphere device - 1

Non-Medical Event

Overexposure

FY17

- PET radiopharmaceutical production - 2 (510 mSv SDE, 110 mSv DDE)
- Cyclotron repair - 1 (940 mSv SDE)
- Release of F-18 from cyclotron vent -1 (120 mSv DDE)

Other Events – Landfill Alarms

- Detection of short lived medical isotopes in municipal waste
- No standard reporting requirement
- Still results in relatively large number of events

2014	2015	2016	2017
113	114	71	18

- Can result in significant response effort
- PA landfill monitoring program

Conclusions

- Relatively small number of Non-Medical events
- Type of events occurring have minimal health and safety impact
- Standardization of landfill alarm response may reduce burden on both regulators and licensees

Acronyms

- CFR – *Code of Federal Regulations*
- Cs-137 – cesium-137
- DDE – Deep Dose Equivalent
- F-18 – flourine-18
- FY – Fiscal Year
- HDR – High dose-rate
- I-125/131 – iodine-125/131
- IR – Interventional Radiology

Acronyms

- mSv – milliSievert
- NMED – Nuclear Material Events Database
- P-32 – phosphorus-32
- PA – Pennsylvania
- PET – Positon Emission Tomography
- RSL – Radioactive Seed Localization
- SDE – Shallow Dose Equivalent

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Can We Learn from past medical events?

Zoubir Ouhib, MS, FACR, FABS
ACMUI Fall 2018 MEETING
September 20, 2018

Agenda

- Lessons learned from medical events (MEs)
- Understand how to use MEs in improving patient safety
- Identify possible corrective actions for a known ME
- Look for possible preventive actions to avoid such ME
- Engage the brachytherapy community in improving patient safety

Disclosure

- None

Facts on Medical Events

- MEs are here to stay and no one is immune
- Similar events are occurring at different facilities
- New events will eventually replace old ones (New technology, upgrades, etc.)
- Question: How can we prevent some and reduce others?

Importance of Information When Reporting Events (Users)

- Need of accurate information and details about the event to find effective solutions
- Details on before(preconditions), during, and after the event are essential
- When reporting events provide facts only and avoid personal interpretation
- Information on software(version),hardware, devices, application, modality, etc.
- Involve all individuals with knowledge about the event

Homework for Everyone (Users)

- Report event to regulatory agency and notify vendor asap.
- Manufacturer to alert (asap) other users once the error is confirmed and provide some clear guidance
- Manufacturer should assist user in evaluating the possible source(s) of event
- User to provide specific and tested corrective actions to be shared with others

Homework for Everyone (Regulators)

- Written and clear statements should be provided
- Preliminary report should be reviewed by the user before going public for accuracy

Proposed Solutions

- Reasonable
- Specific
- Practical
- Proven
- Have been evaluated to avoid for new errors

Medical Event Project

- Select an ME (based on its impact and frequency)
- Share the event with users for input on corrective and preventive actions
- Tabulate collected solutions and share them with the brachytherapy community
- Solutions are reviewed by an ABS select team

Medical Event Project (Cont'd)

- Ensure that final recommendation is shared among all users: ABS website and available to AAPM, ASTRO, IAEA, manufacturers
- Track these specific errors and evaluate effect of information sharing
- Encourage users to share similar near misses errors

First Case: Incorrect Source Transfer Tube Length

- Case description sent to users
- Specific feedback requested from users
- Provided with e-mail where to send the feedback

Intent of the Project

- Improve patient safety
- Involve as many users as possible for best possible solutions
- Involve Manufacturer for better solutions and improvements
- Share solutions with the brachytherapy community

Questions to Participants (users) for Case 0001

When you are considering corrective actions try answering the following:

1. *What safety barrier failed to identify the incident?*
2. *What possible safety barrier identified the incident?*
3. *What safety barrier might have identified the incident?*
4. *What possible factors contributed to the incident?*

Questions to Participants (Cont'd)

These questions can lead you to address the key question:

What preventive action(s) could stop reoccurrence of a similar event?

Users' feedback to be sent to

PreventMedEvent@gmail.com

Monitored by
Sarah Smith
and
Panagiota Galanakou

Motivation Line

"Noticing that something is broken is an essential prerequisite for coming up with a creative solution to fix"

—**Tom Kelley**, **Creative Confidence: Unleashing the Creative Potential Within Us All**

Information Sent to Users

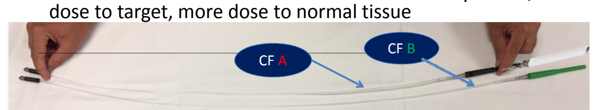
Medical event case 0001

Patient safety is a critical goal for all of those involved in delivering brachytherapy treatment. Safety reporting followed by analysis of any errors in treatment delivery are essential steps in optimizing patient safety. The series of Brachyblast submissions will focus on sharing brachytherapy events with the ABS membership to prevent any future events. We are two graduate Medical Physics students at a CAMPEP accredited institution who share an interest in both brachytherapy and patient safety. We are directly overseen by Zoubir Ouhib who, along with the ABS Patient Safety Committee, has graciously allowed us to pursue this task.

Over the next few months, you will be presented with a series of medical events in brachytherapy that have occurred around the world. Please be aware that the details on the reporting information might not be as complete as we hope to have. Your objective will be to suggest corrective action for each event. We also welcome any preventive actions that you might have in place to prevent such events from occuring. The responses received will then be prioritized and disseminated with the goal of sharing a focus on patient safety culture. Without further ado, here is your first case:

Summary of Case (11 Patients)

- HDR unit commissioned with "click-fit A"
- Institution received later Miami applicator with "click-fit B" for all three catheters (tandem and ovoids)
- "Click-fit B" is 10 cm longer than Click-fit A
- One of the "Click-fit A" (central channel/Tandem) broke; new plan using "click-fit B" was generated for treatment
- Therapists instructed to use Click-fit B for tandem only
- Miscommunication led to the use of Click-fit B for all three catheters (not just tandem).
- Results: dose from ovoids inferior than desired by 10 cm; less dose to target, more dose to normal tissue



Summary of Case 2 (Additional 57 Patients)

- While investigating previous event additional error was discovered
- Actual total length for "Click-fit B" is 133.5.
- For Planning purpose: length for Tandem should be= 133.5 - 1.4 cm=132.1 cm (1.4 cm accounts for the quick connect part of the HDR unit)
- For planning, default value of 130 cm was used vs. 132.1 which should have been measured
- Results: previous 11 patients received treatment at 2.1 cm (132.1 - 130) further lower (10 + 2.1=12.1 cm) than prescribed and additional 57 patients at 2.1 cm lower than prescribed

Information Sent to Users

Wrong Source Transfer Tube Length

Introductory Information: Reported to SAFRON on October 31, 2016, this major incident affected 68 patients treated with the Varian Varisource iX HDR afterloader & planned with BrachyVision V13.5. The event was discovered post treatment completion by the radiation oncologist during a clinical review of the patient. The range of dose deviation was 20-50% of the prescribed dose. Two related errors that occurred will be discussed.

This afterloader model accommodates variable length catheters, and as a pre-treatment check, performs a channel too short test, but not a channel too long test. The vendor also provides source transfer tubes of various lengths, through which the source is transferred between the afterloader and applicators. The transfer tubes attach to the applicators or needles using a "click-fit" connector, and to the afterloader using a "Quick-Connect" mechanism.

Error 1 (11 patients): The Varisource iX HDR system was commissioned with a click-fit set of predefined length named "Click-fit Set A". A few months following commissioning, a new Miami applicator was procured with a new "Click-fit set B" that is 10cm longer than "Click-fit set A". In July 2016, the central channel of "Click-Fit set A" broke and the planning team decided to use the transfer tube from "Click-Fit Set B" until it can be replaced. Hence the planning team planned treatments using "Click Fit Set B" for the central channel and used "Click fit Set A" for the two ovoids. The above was communicated to the radiotherapists responsible for connecting the Click-fit tubes and administering the treatment of the patients. Unfortunately, some radiotherapists misunderstood the change and thought all 3 connections must now use "Click-Fit Set B". This resulted in 11 patients being treated on the ovoids 10 cm lower than they should have been treated. An in-depth investigation was done on all brachytherapy patients treated from June 2016. All affected patient plans were re-planned to include the error showing the differences in doses from what was prescribed and what was administered. This error unfortunately resulted in major differences in planned vs. delivered dose.

Information Sent to Users

Error 2 (57 patients): During investigation of Error 1 it was decided to remeasure and confirm lengths of all the brachytherapy transfer tubes and applicators used at this facility. During this verification it was found that the length of the Tandem (channel 1) for the Miami applicator was incorrectly entered in the TPS (Treatment Planning System). When using "Click-fit set B" the length of the transfer tube with the tandem of the Miami applicator measured 133.5 cm. The vendor confirmed the measurement of 133.5 cm. Therefore, the planning applicator length should be 132.1 cm (the extra 1.4 cm accounts for the Quick Connect part of the machine). The planning team was using 130 cm planning length instead of 132.1 cm. The 130 cm that had been used to plan the patient plans was a default applicator length and was also used in the BrachyVision demo plans. This hadn't been manually measured or tested at this facility after the new applicator was procured. This resulted in all patients in error 1 being treated a further 2.1 cm lower that prescribed and an additional 57 patients also treated 2.1 cm lower that what was required. All affected patient plans were re-planned to include the error showing the differences in doses from what was prescribed and what was administered.

Information Sent to Users

When you are considering corrective actions try answering the following:

1. What safety barrier failed to identify the incident?
2. What possible safety barrier identified the incident?
3. What safety barrier might have identified the incident?
4. What possible factors contributed to the incident?

These questions can lead you to address the key question: **What preventive action(s) could stop reoccurrence of a similar event?**

Please send corrective action suggestions before August 6, 2018 to: PreventMedEvent@gmail.com including the title of the event (or case #), your name, your institution (Optional), and your profession (Med. Phys., Rad. Onc., etc.).

We are eager to receive your reply on how you would have dealt with the situation if it had occurred in your institution and what you have in place that would have prevented similar events. Please look for our follow up report in next month's Brachyblast where we will present the committee's selected responses. The next medical event case (0002) will be presented in the following Brachyblast newsletter. Thank you in advance for your feedback that will make a difference.

"Noticing that something is broken is an essential prerequisite for coming up with a creative solution to fix"
— Tom Kelley, Creative Confidence: Unleashing the Creative Potential Within Us All

Sarah Price and Panagiota Galanakou

Summary of Feedback (Users)

Case 0001 Responses and Feedback from Brachyblast Readers:

Sarah Price, Panagiota Galanakou, and Zoubir Ouhib MS FACR, FABS

As promised in our case 0001 posted on the Brachyblast on July 31st 2018, we are eager to present the feedback (corrective and preventive measures) that we have collected from several colleagues (medical physicists and radiation oncologists). As a reminder to readers, this is a case of an HDR procedure where the use of an incorrect length (incorrect click-fits and wrong input into the TPS) has led to a medical event.

Feedback From Users

Immediate (Short Term) Actions	
Corrective	**Preventive**
Independent manual measurement check to verify treatment length matches planning length.	When a different than manufacturer recommended click-fit is to be used as a substitute with any applicator, a commissioning should be performed in advance using manufacturer recommended length (confirmed with measurement by the user).
Policies and procedures that require the medical physicist to be directly involved with the treatment set up when there are any alterations to the plan, HDR equipment, or treatment devices.	All members of the brachytherapy team should be directly informed regarding any modifications to the use of device or treatment plan. In addition to verbal instructions, written ones with photos of selected click-fit set used for planning should be provided for treatment setup verification and delivery.
In-service for the brachytherapy team regarding the use of "Click-fit" with all applicators and the clinical impact when using the non-planned one.	The physicist involved in the modification of any treatment plan should directly be involved in the patient setup prior to treatment. The resulting set up should be independently be verified by the treatment team.
	When there is any doubt about proper set up and use of brachytherapy device, time-out should be performed and manufacturer should be contacted for clarification and recommendation prior to treatment
	When having two different sets of click-fit (A and B) consider retiring one set to eliminate the use of the wrong one. The resulting total length when connected to this selected click-fit set remains a variable and one should consider a table of total length for all applicators as a reference for treatment planning.

Feedback From Users

Long Term Actions
Manufacturers should consider redesigning the afterloader to measure (in the dummy sequence) each treatment length and stop treatment if the measured value is not within 1mm of the planning length.
Manufacturers should remove the legacy 'magic' numbers (the 1.4 cm difference between the actual measurement of treatment length with a Quick Connect for VariSource iX and the actual treatment length).
Manufacturer should remove the default treatment length from the BrachyVision TPS. The user should be forced to enter the length and there should be an authorization popup requiring initials (or password) to proceed. This will ensure measurements were performed.
Click-fits should be designed and sold such that they have the same length for all applicators.
Manufacturers should provide illustrations or demonstrations of the possible ramifications of improper use of devices and various click-fit set. For this specific example, demonstrate how using an incorrect click-fit set will result in a medical event. During training, emphasis should not only be on how things work well but also how things can lead to medical events. Reported events should be part of the education with demonstration.
Manufacturers should provide detailed illustrations or demonstrations of the procedures the staff should follow for proper treatment.
Treatment summary generated by the plan that will include all critical parameters for treatment setup and delivery will be useful. Parameters such as patient name, applicator model, "click-fit" set, planning length, fraction #, and dose.

Information Sent to Users

We encourage our readers to continue to submit their ideas to PreventMedEvent@gmail.com as there may have been other preventive and corrective actions we did not identify. Be sure to check out next month's BrachyBlast where we will present case 0002.

Acronyms

- AAPM: American Association of Physicists in Medicine
- ABS: American Brachytherapy Society
- ASTRO: American Society for Radiation Oncology
- CAMPEP: Commission on Accreditation of Medical Physics Education Programs
- IAEA: International Atomic Energy Agency
- ME: medical event

Acknowledgement

- Donna-Beth Howe, Ph.D. Medical Radiation Safety Team, NRC
- IAEA (Debbie Gilley)
- Sarah Smith and Panagiota Galanakou, FAU graduate students
- Wesley Culberson Ph.D., Robert Ebeling III M.D., Stephen J. Klash, Dorin Todor Ph.D., Daniel Scanderbeg Ph.D., Christopher L. Deufel Ph.D., and William Bice Ph.D.

Training and Experience for All Modalities

Darlene Metter, M.D.
Advisory Committee on the Medical Uses of Isotopes
September 20, 2018

Subcommittee Members

Philip Alderson, M.D.
Darlene Metter, M.D. (Chair)
Michael Sheetz
Megan Shober, M.S.
John Suh, M.D.
Laura Weil, M.S.

T&E Subcommittee

- Created standard approach and template for T&E review
- Completed review of 10 CFR 35.100
- Concern raised about patient access, so 10 CFR 35.300, specifically 10 CFR 35.390 was expedited for review.

March 2018 ACMUI

- New subcommittee concern
  Potential future AU shortage
- 2 new developments
  - FDA approval of ^{177}Lu dotatate may increase therapeutic procedures
  - Decrease in candidates for ABNM initial certification exam

T&E Subcommittee Concern

- Potential increase in procedures with concurrent decrease in AU
  - Potential future AU shortage
- Recommendation
  Consider an alternate AU pathway

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Current Status

- After revision of 10 CFR Part 35 (08/2017), Commission tasked the NRC staff to investigate the feasibility of a limited AU pathway, specifically for radiopharmaceutical therapy.
- Commission to be updated every 6 months. First report: August 2018

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Tasks for A Limited AU Pathway

- Feasibility for certain categories of radiopharmaceuticals
- How to develop these categories
- Appropriate T&E requirements
- Competency: based on number of hours or objective measure (examination)

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Work on Limited AU Pathway

- NRC staff assessing feasibility of limited AU pathway with tailored T&E and documentation of competency.
- Continuing broad stakeholder input.

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Feasibility

- NRC staff developed draft of potential knowledge topics needed for AU.
- ACMUI subcommittee input

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Proposed Curriculum

- Knowledge topics in 10 CFR 35.390 were used as a starting point
- Potentially tailored to specific RP
- Potential need for additional knowledge topics

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Initial Stakeholder Input

- Due to time constraints, initial stakeholder outreach was limited.

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Initial Stakeholder Response

- Need fundamental & specific RP knowledge in 10 CFR 35.390 to safely administer RP – Support
- How to obtain this knowledge – varied responses
- How to evaluate the independent application of this knowledge- varied

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Stakeholder Concerns

- How to categorize RP
- How to administer T&E
- How many T&E hours
- How to assess competency- develop exam by medical community with or without preceptor attestation; new certification boards?

NRC Staff Conclusion

- It may be feasible to develop a limited AU status for certain RP with tailored T&E and competency-based assessment of knowledge and skills obtained.

ACMUI Subcommittee Review

- Broader stakeholder outreach needed for potential limited AU status.
- Need to define: RP categories, limited T&E and competency assessment for knowledge and skills obtained.

Subcommittee Review

- Collaborate with medical community in developing a competency-based assessment tool.
- Minimizing T&E may jeopardize patient, staff and public safety.

Subcommittee Review

- Initial underestimation of available AU for 10 CFR 35.390
- ACGME: ~ 900 (Radiation oncology nuclear medicine, nuclear radiology, redesigned ABR path)
- AOBR: 150-200

Subcommittee Review

- Feasibility of alternate AU pathway should still be explored.
- Concern about estimating number of T&E hours. T&E requirements should be based on necessary knowledge and skills, not on hours.

Subcommittee Recommendations

- Review existing AU pathways to maintain safety, maximize patient access and clearly define AU scope of practice.

Subcommittee Recommendations

- T&E must be inclusive:
- Comprehensive coverage of radiation physics , radiation biology, radiation instrumentation & mathematics; radiation protection & safety, patient release; applicable regulations & ME

Subcommittee Recommendations

- AU competency must be determined objectively for initial assessment and for maintenance of competency.
- Greater stakeholder input needed.

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Subcommittee Recommendations

- NRC staff should monitor potential AU shortage for 10 CFR 35.300:
  Include geographic data and practice patterns as part of the monitoring.

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Subcommittee Current Plans

- Work with NRC staff to
  - Expand stakeholder outreach
  - Explore feasibility of limited AU pathway(s)

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Subcommittee Future Work

- Subcommittee plans to work with the NRC staff if the NRC plans to propose changes to the current T&E requirements as a result of its assessment.

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Subcommittee Future Work

- T&E core requirements:
  - Adequate acquisition & application of the knowledge & skills for appropriate RP use & administration while ensuring patient, staff and public safety.

Subcommittee Plans

- Work with NRC staff to determine how best to assess competency.

Acronyms

- ABNM – American Board of Nuclear Medicine
- ABR – American Board of Radiology
- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- AOBR – American Osteopathic Board of Radiology
- AU – Authorized User
- CFR – Code of Federal Regulations

Acronyms

- FDA – US Food and Drug Administration
- ^{177}Lu – ^{177}Lutetium
- ME – Medical Event
- NRC – Nuclear Regulatory Commission
- RP – Radiopharmaceutical
- T&E – Training and Experience

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Training & Experience Stakeholder Outreach Plan

Maryann Ayoade
Medical Radiation Safety Team, NMSS
September 20, 2018

Purpose

- To conduct more extensive outreach with the medical community focused on assessing options to tailor the T&E requirements for medical uses authorized under 10 CFR 35.300

Background

- In SRM-M170817, the Commission directed the NRC staff to evaluate:
  - Whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals
  - How those categories should be determined
  - What the appropriate T&E requirements would be for each category
  - Whether those requirements should be based on hours of T&E or competency

Background (Cont'd)

- Evaluation included limited outreach in April/May 2018
- Information SECY paper conclusion:
  - It may be feasible to establish tailored T&E requirements for different categories of radiopharmaceuticals and to create a means of authorizing the administration of certain categories of radiopharmaceuticals (limited AU status)
  - There are viable options for creating a competency-based approach to demonstrate acceptable T&E for limited AUs
  - Staff plans to conduct more extensive outreach

Outreach Activities

- *Federal Register* notice with questions
- Public meetings/webinars
- Website
- Letters/e-mails
- Posters/presentations
- Newsletter articles

Additional Information Gathering

- Evaluation of AU shortage
- Review of medical and radiation safety events
- International benchmark

Stakeholders

- Licensees
- Regulators (Agreement States, FDA, CMS, international agencies)
- Medical Specialty boards
- Patient health organizations/advocacy groups
- Trade organizations/industry groups
- Medical professional societies
- Medical specialty training/fellowship organizations
- Medical oncology community

Federal Register Notice Questions

- Questions regarding establishing tailored T&E requirements for radiopharmaceutical uses requiring a written directive
- Questions regarding the assessment of knowledge, skills, and abilities
- Questions regarding patient access

Next Steps Following Outreach

- Analyze public comments/information
- Continue to engage ACMUI
- Keep Commission informed of outreach efforts
- Determine whether changes to current T&E requirements are warranted

Acronyms

ACMUI – Advisory Committee on the Medical Uses of Isotopes

AU – Authorized User

CFR – Code of Federal Regulations

CMS – Centers for Medicare & Medicaid Services

FDA – U.S. Food and Drug Administration

NMSS – Office of Nuclear Material Safety and Safeguards

NRC – U.S. Nuclear Regulatory Commission

SRM – Staff Requirements Memorandum

T&E – Training and Experience

Joint ACMUI SNMMI Session: What's Up for You and Your Patients?

D. Metter, M.D.
C. Palestro, M.D.
S. Daibes Figueroa, Ph.D.
June 25, 2018

Joint ACMUI SNMMI Session: What's Up for You and Your Patients?

- Introduction & Overview: D. Metter
- Requirements for Training & Experience for Authorized Users: C. Palestro
- Patient Release Project for ^{131}I: C. Palestro
- Guidelines for Nursing Mothers: D. Metter
- Question and Answer: D. Metter, C. Palestro, S. Daibes Figueroa

Joint ACMUI SNMMI Session: What's Up for You and Your Patients?

- Topics selected based on SNMMI feedback
- CME and SAM session
- Well attended
- Engaged audience with excellent dialogue between audience and speakers
- Should be held on an ongoing basis

Acronyms

- ACMUI: Advisory Committee on Medical Uses of Isotopes
- CME: Continuing Medical Education
- SAM: Self Assessment Module
- SNMMI: Society of Nuclear Medicine and Molecular Imaging

Nursing Mother Guidelines for the Medical Administration of Radioactive Materials

Darlene Metter, MD, FACR
September 20, 2018

Subcommittee Members

- Vasken Dilsizian, M.D.
- Darlene Metter, M.D. (Chair)
- Christopher Palestro, M.D.
- Pat Zanzonico, Ph.D. (previous member)

The Nursing Mother

- Breast feeding is the feeding of an infant from the female breast.
- Lactation is the process of milk production.
- Lactation ceases 6 weeks after the last breast-feeding.

Nursing Mother Guidelines

- Charge: "Review the radiation exposure from diagnostic and therapeutic radiopharmaceuticals, including brachytherapy, to the nursing mother and child."

Radiation Safety for the Nursing Mother

- ALARA principle is the NRC guidance on radiation safety.
- Many NM procedures are elective, thereby allowing a temporary or at times complete cessation of nursing.

Patient Release

- Patient release (nursing mother): Total EDE to any individual (nursing child) is < 5 mSv.
- If exposure could exceed 1 mSv, written instructions of adverse consequences must be given (to include written instructions) if nursing is not stopped and guidance on the discontinuation of breast feeding. (10 CFR 35.75)

Radiopharmaceuticals

- Many drugs & radiopharmaceuticals (RP) enter breast milk
- < 10% (~0.3-5%) enter breast milk
- Ten physical half-lives = 99.999% of a radionuclide's decay

Radiopharmaceuticals in Breast Milk

- Most RP administered require a temporary cessation of breast feeding.
  - Pumped radioactive breast milk can be held for 10 physical half lives before feeding to the nursing child.
- A few RP administered may require complete cessation of breast feeding.

Radiopharmaceuticals in Breast Milk

- **Exception**: (to decrease the breast dose)
- ^{131}I-NaI dose to the lactating breast
  - ^{131}I-NaI 150 mCi = 200 R (breast)
- ^{131}I-NaI requires cessation of breast feeding 6 weeks prior to RP administration (to cease lactation) & for that child. May breast feed in the future.

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Radiation Exposure During Nursing

- Mother: Internal
- Child: External and Internal

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Radiation Exposure: Nursing Child

- **External**: Mother is a significant source
- <u>ALARA</u>:
- Time: increased
- Distance: decreased
- Mother can be a significant radiation source of exposure to the nursing child, especially during routine child care.

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Radiation Exposure: Nursing Child

- **Internal**:
- Ingested radioactive breast milk
- Depends on the RP (~0.3-5% in milk)
- ^{131}I-NaI: Cease breast feeding 6 weeks* before administration & for the current child.
- May breastfeed for future children.

* Lactation ceases 6 weeks after the last breastfeeding

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Nursing Mother Recommendations

Nursing interruption	Radiopharmaceutical
• Stop	• ^{131}I-NaI*, ^{124} I-NaI, alpha, ^{177}Lu –OCTREOTATE diagnostic or therapy
• None	• ^{15}O, ^{82}Rb
• 1 hour	• ^{11}C, ^{13}N
• 4 hours	• ^{18}F, ^{68}Ga

Nursing Mother Recommendations

Nursing interruption	Radiopharmaceutical
• 24 hours	• ^{99m}Tc
• 3 days	• ^{123}I-NaI
• 4 days	• ^{201}Tl-chloride
• 6 days	• ^{111}In-WBC, -OCTREOTATE
• 28 days	• ^{67}Ga, ^{89}Zr

Duration of Discontinuation of Breast-Feeding to Achieve Specified Dose Limits to Newborn Tissue

Radiopharmaceutical	A [a] (mCi)	Dose-limiting Newborn Tissue	Duration of Discontinuation of Breast-feeding to Achieve the Following Dose to the Dose-limiting Newborn Tissue: 0.1 rad	0.5 rad
^{11}C-Any radiopharmaceutical	25	Whole body	1 h	No discontinuation
^{13}N-Any radiopharmaceutical	25	Whole body	1 h	No discontinuation
^{15}O-water	50	Whole body	1 h	No discontinuation
^{18}F-FDG	10	Whole body	4 h	No discontinuation
^{67}Ga-citrate	5	Whole body	31 d	23 d
^{68}Ga-octreotate	5	Whole body	No discontinuation	No discontinuation
^{82}Rb-chloride	60	Whole body	No discontinuation	No discontinuation
^{99m}Tc-Any radiopharmaceutical	10	Whole body	16 h	4 h
	20	"	24 h	8 h
	30	"	32 h	16 h
^{111}In-octreotate	5	Whole body	5.7 d	7.5 d
^{111}In-white blood cells	5	Whole body	5.7 d	7.5 d
^{123}I-ortho-iodohippurate (OIH)	1	Whole body	4 h	No discontinuation
^{123}I-meta-iodobenzylguanidine (MIBG)	11	Whole body	No discontinuation	No discontinuation
^{123}I-iodide	0.4	Thyroid	2.7 d	1.5 d
^{124}I-iodide	2	Thyroid	28 d	21 d
^{131}I-ortho-iodohippurate (OIH)	0.27	Whole body	4 h	No discontinuation
^{131}I-meta-iodobenzylguanidine (MIBG)	2	Whole body	7.8 d	3.2 d
^{131}I-iodide	2	Thyroid	32 d	26 d
^{177}Lu-octreotate	50	Whole body	19 d	12 d
	211	"	27 d	19 d
^{201}Tl-thallous chloride	4	Whole body	4.3 d	No discontinuation

Sealed Sources

- Y-90 Microspheres: No interruption
- Breast & sentinel lymph node sources: No interruption as long as source(s) is(are) not in the nursing mother

NM Department Signage

- Inform nursing mothers or mothers planning to nurse in the near future who are scheduled for a NM procedure, that certain RP may require radiation safety precautions.
- Such patients are advised to notify the NM staff or physician prior to their procedure.

Final Report

- The Subcommittee presented its draft report during the February 1, 2018 public ACMUI teleconference meeting.
- The report was endorsed by the full Committee with some caveats (e.g., calculations, modifications to tables).
- Recommendation: For the full Committee to endorse the final report as presented.

Acronyms

- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- ALARA – As Low As(Is) Reasonably Achievable
- CFR – *Code of Federal Regulations*
- EDE – Effective Dose Equivalent
- NM – nuclear medicine
- NRC – Nuclear Regulatory Commission
- R – Rad
- RP – Radiopharmaceuticals

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ACMUI Comments on the Draft Revision of the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife ® Icon ™ Licensing Guidance

John Suh, M.D.

ACMUI Radiation Oncologist

September 20, 2018

Subcommittee Members

- Ronald Ennis, M.D.
- Zoubir Ouhib*, M.S.
- Megan Shober*
- John Suh, M.D. (Chair)
- Laura Weil

NRC Staff Resource: Sophie Holiday

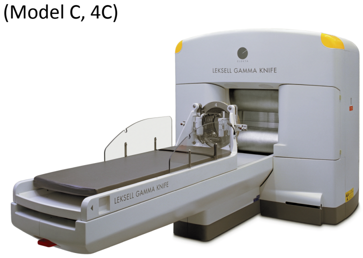
* Joined subcommittee 7/1/2018

Subcommittee Charge

- To propose the appropriate physical presence requirement for the Leksell Gamma Knife® Icon™ radiosurgery unit.

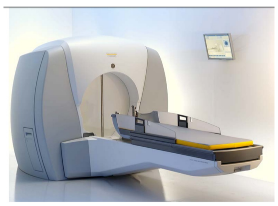
Leksell Gamma Knife®

- Gamma Knife ® Model B, C, and 4C
  - 201 Co-60 sources are stationary
  - External helmets (4, 8, 14 and 18 mm)
  - Manual trunnions (Model B) or Automated Positioning System (Model C, 4C)



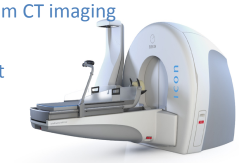
Leksell Gamma Knife®

- Gamma Knife® Perfexion™ (2006)
  - 192 Co-60 sources move within 8 permanently installed, independent movable sectors for 4, 8, and 16 mm beams
  - One collimator body with different diameter of holes corresponding to the different positions of the sectors
  - Automated movement of the robotic treatment table



Leksell Gamma Knife®

- Gamma Knife® Icon™ (2016)
  - 192 Co-60 soures move within 8 permanently installed, independent movable sectors for 4, 8, and 16 mm beams
  - One collimator body with different diameter of holes corresponding to the different positions of the sectors
  - Automated movement of the robotic treatment table
  - Integrated stereotactic Cone-beam CT imaging
  - Online Adaptive DoseControl™
  - Frameless mask-based treatment



Background About Current Regulations

- All Leksell Gamma Knife® procedures follow the physical presence requirements in 10 CFR Part 35.615 f(3), that "an authorized user (AU) and an authorized medical physicist (AMP) are physically present throughout all treatments involving the unit".
- NRC defines "physical presence" as the distance "such that each can communicate with the other within hearing distance of normal voice".
- Models B, C, and 4C are licensed under 10 CFR 35.600
- Perfexion™ and Icon™ are licensed under 10 CFR 35.1000

Feb. 2018 Subcommittee Recommendations

Based on the very low number of reported MEs with the Perfexion™ (12 from 2006-2012) and the advances with the Icon™ unit, the subcommittee recommends:

1) AU and AMP be physically present during the initiation of all treatments involving the unit.

2) AMP be physically present throughout all patient treatments involving the unit.

Feb. 2018 Subcommittee Recommendations

3) The current physical presence requirements for the AU be modified by allowing the AU to be present within a two minute walk to the console area, **and** immediately available to come to the treatment room. In addition to the AU and AMP, we recommend as matter of good medical practice that appropriately trained nursing or auxiliary staff be present at Gamma Knife® treatment to respond to any immediate medical needs.

4) At the conclusion of treatment, the AU must be present at the Gamma Knife® console to discuss any treatment or patient issues with the patient, physicist, and nurse.

Working Group's Recommendations

- The working group (WG) reviewed the subcommittee report and recommendations, submitted comments from Elekta and Michael Sheetz (ACMUI RSO); however, the WG proposed revisions to the guidance.
- The WG and management were not supportive of the 2 minute walk as they felt this was very ambiguous. The proposed physical presence requirements is similar to that of HDR brachytherapy. In addition, the proposed requirements included both the Perfexion™ and Icon™ units.

Working Group's Recommendations

1) An AU and an AMP will be physically present during the initiation of all patient treatments involving the Perfexion™ or Icon™ unit;

2) An AMP and either an AU or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, will be physically present during continuation of all patient treatments involving the Perfexion™ or Icon™ unit; and

Working Group's Recommendations

3) An AU will return to the Perfexion™ or Icon™ unit console if there is an interruption of treatment to evaluate the patient, to review any information related to an abnormal situation, and to ensure that the treatment is being delivered in accordance with the treatment plan and written directive prior to re-initiation of the treatment.

Subcommittee's Current Recommendations

- An AU and AMP will be physically present during the initiation of all patient treatments involving the Perfexion™ or Icon™ unit
- Since the proposed physical presence requirements is similar to that of HDR brachytherapy, the subcommittee believes this definition is not ambiguous and will be easier to enforce that the 2 minute walk from the console area.

Subcommittee's Current Recommendations

- An AU will return to the Perfexion™ or Icon™ unit console if there is an interruption of treatment.
- Since the Perfexion ™ and Icon™ are licensed under 10 CFR Part 35, Subpart K (10 CFR 35.1000) and are mechanically similar, the subcommittee endorses the draft revision to the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ to include the same physical presence requirements for both units.

Subcommittee's Current Recommendations

- Although the scope and recommendations are different than the ACMUI subcommittee report, we endorse the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ licensing Guidance.
- Licensees are encouraged to continue to audit and monitor their programs and adopt best practices including a high reliability system approach.
- The ACMUI and NRC review any negative trends that may occur as result of a change in guidance.

QUESTIONS?

Acronyms

- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- AMP- Authorized Medical Physicist
- AU – Authorized User
- CFR – *Code of Federal Regulations*
- HDR – High Dose Rate [Remote Afterloader]
- ME – Medical Event
- NMED – Nuclear Medical Events Database
- NRC – U.S. Nuclear Regulatory Commission
- SRS – Stereotactic radiosurgery
- WG – working group

Nuclear Regulatory Commission (NRC)
<u>Advisory Committee on the Medical Use of Isotopes (ACMUI)</u>

Subcommittee Review and Comments on

Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Draft Licensing Guidance, Revision 1

Submitted on: August 31, 2018

Subcommittee Members:
Ronald Ennis, M.D.
Zoubir Ouhib, M.S.
Megan Shober
John Suh, M.D. (Chair)
Laura Weil

NRC Staff Resource: Sophie Holiday

Background: The subcommittee and its Chair were appointed by ACMUI Chair, Phil Alderson, at the regularly scheduled ACMUI meeting on April 26, 2017. This subcommittee was formed after a presentation on April 26, 2017 by Elekta, Inc. requesting emendation of the Title 10 of the *Code of Federal Regulations* (10 CFR) 35.1000 licensing guidance for the Leksell Gamma Knife® Icon™ to allow the authorized user (AU) to be physically present in the department during patient treatment and immediately available to come to the treatment room to respond to an emergency based on the very small number of medical events (MEs) that have occurred with modern Gamma Knife® units. The charge to subcommittee: was to propose the appropriate physical presence requirement for the Leksell Gamma Knife® Icon™ (hereafter referred to as Icon™) gamma stereotactic radiosurgery unit.

The initial report was presented on September 12, 2017 at the ACMUI meeting. An updated report was provided on February 1, 2018 based on feedback from the ACMUI meeting in September 2017. The subcommittee provided its recommendations during the February 15, 2018 public teleconference call regarding the physical presence requirements for the Icon™.

The NRC/Agreement State Working Group (WG) reviewed the report and recommendations, the ACMUI meeting transcripts, and submitted comments from Elekta and Michael Sheetz (ACMUI Radiation Safety Officer). The WG's proposed revisions to the guidance was submitted to the subcommittee for review and comment. The WG proposed physical presence requirements similar to that of the high dose rate (HDR) remote afterloader unit where the AU is present at the initiation of the treatment; and an AU or a physician under the supervision of the AU is present during the continuation of the treatment. In addition, the AU will return to the console if there is an interruption of treatment to evaluate the patient, review any information related to an

abnormal situation, and to ensure that treatment is in accordance with the treatment plan and written directive.

The original subcommittee, along with Megan Shober and Zoubir Ouhib who were added to the subcommittee on July 1, 2018, reviewed the draft revision of the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance.

Since the draft revision of the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance is different than the recommendation of the subcommittee report from February 2018, this document will provide a summary of the original subcommittee recommendations, current physical presence requirements, rationale for change, and review and comments of the draft guidance.

Summary of Subcommittee Recommendations for Physical Presence Requirements for the Leksell Gamma Knife® Icon™ (*submitted February 2018*)

1. The AU and authorized medical physicist (AMP) need to be physically present during the initiation of all treatments. This allows independent confirmation that the correct plan is being used for treatment and that the correct site is being treated during the initiation of treatment.

2. The current physical presence requirements for the AU be modified by allowing the AU to be present in the department during treatment, which is defined for the Icon™ as within a two minute walk to the console area, and immediately available to come to the treatment room. An AMP needs to be physically present during the entire treatment. While we recognize the NRC does not have regulations for nursing or auxiliary staff, we recommend as a best practice that appropriately trained nursing or auxiliary staff be present at Gamma Knife treatment to respond to any immediate medical needs. It should be the responsibility of the AU to determine the necessary training and experience required of the nursing staff.

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

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

Current Physical Presence Requirement

In October 2002, the NRC modified the regulations in 10 CFR Part 35 to include a section[1] regarding gamma stereotactic radiosurgery to include the requirement that “For gamma stereotactic radiosurgery unit, require an Authorized User with appropriate training and experience in radiation oncology and Authorized Medical Physicist to be physically present

[1] 10 CFR 35.615(f)(3)

throughout all patient treatments involving the unit." This regulation provided for an appropriate response to an emergency and to ensure that the correct dose of radiation is delivered to the patient. The term[2] "physically present" was defined as "within hearing distance of normal voice".

The NRC issued a Regulatory Issue Summary (RIS) to clarify the definition of "physically present" as a result of an event at one of the Gamma Knife centers. The RIS (RIS-2005-23)[3], "Clarification of the Physical Presence Requirement During Gamma Stereotactic Radiosurgery Treatment," stated that this meant speaking in a normal conversational tone and not a raised voice. As a result, a distance of 20 feet may not be close enough to adequately hear and respond to an emergent situation. This also ensures the correct dose of radiation was delivered.

Rationale for change

The current definition ensures that an emergent situation will be addressed immediately by the AU and that the correct dose is delivered. The AU has the knowledge and appropriate training to ensure the safe and effective delivery of stereotactic radiosurgery treatment. The current physical presence definition is not ambiguous and ensures the AU is present for the all the critical portions of the procedure, able to address any medical issues that may arise during treatment, and verify the correct dose will be delivered to the target(s). The AU will have the competency to recognize and respond to any aberration of treatment and ensure response times within seconds if needed.

Medical issues during the Gamma Knife® treatment may include pain from the frame, nausea, vomiting, and seizure. Incorrect dose of radiation may result secondary to system failure which could be software, hardware, or combination of both. As serious medical issues and/or significant aberrations in treatment can result in reportable MEs, rules regulating physician presence exist to ensure patient safety.

Over the past ten years of NMED, there are 12 reportable events involving the Leksell Gamma Knife Perfexion™ (hereafter referred to as Perfexion™). Of the 12 Perfexion™ reportable events, only a minority were identified during treatment. The Icon™ unit has significant enhancements over the Perfexion™ unit. Specifically, three features are important: 1) the option of treatment with a thermoplastic frameless mask rather than a frame; 2) ability to perform integrated stereotactic cone-beam computed tomography (CBCT) which provides stereotactic reference for patient setup; and 3) high definition motion management (HDMM) for mask-based treatments. These enhancements re-open the question regarding the physical presence requirements of the AU for the entire treatment. A review of the 12 events for Perfexion™ reveals that none of these events would have escaped detection on an Icon™ unit using the thermoplastic frameless mask and HDMM for mask-based treatments even if the AU was not physically at the console and could have been rapidly and effectively addressed as long as the AU was immediately available.

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[2] Section V, Summary of changes of 2002 revised part 35 in *Federal Register* (67 FR 20355)
[3] NRC-issued Regulatory Issues Summary (RIS) 2005-23 – October 2005

Based on the extremely low number of MEs with the Perfexion™ unit coupled with the modifications with the Icon™, the subcommittee recommended modifying the current physical presence requirements for the Icon™ unit.

Working Group's Draft Licensing Guidance for Perfexion™ and Icon™

Physical Presence Requirements Recommended in the Draft Licensing Guidance Document

1. An authorized user and an authorized medical physicist will be physically present during the initiation of all patient treatments involving the Perfexion™ or Icon™ unit;

2. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, will be physically present during continuation of all patient treatments involving the Perfexion™ or Icon™ unit; and

3. An authorized user will return to the Perfexion™ or Icon™ unit console if there is an interruption of treatment to evaluate the patient, to review any information related to an abnormal situation, and to ensure that the treatment is being delivered in accordance with the treatment plan and written directive prior to re-initiation of the treatment.

Similarities Between the Working Group and Subcommittee's Recommendations for Physical Presence Requirements

1. An AU and AMP will be physically present during the initiation of all patient treatments. The subcommittee fully agrees with the requirement to have AU and AMP present during initiation of all treatments. If the decision is made to incorporate the Perfexion™ or Icon™ unit under the same licensing guidance, it is important to stipulate that the AU be present for the initiation of every fraction to maximize quality and safety. Since the Icon™ unit allows for multiple treatments (2-5 fractions) during the week, the AU and AMP need to be present at the initiation of every fraction, not just the first fraction of treatment.

2. An AU will return to the console if there is an interruption of treatment.
Since a greater number of patients are being treated with Gamma Knife® radiosurgery, may have longer treatment times secondary to the number of brain lesions being treated, and/or may undergo multiple sessions with the Icon™ unit, the likelihood of an interruption of treatment secondary to a medical issue or patient comfort increases. As a result, it is important that the AU is present to evaluate the patient's condition if needed, to review any information related to an unexpected occurrence, and to ensure the treatment is being delivered in accordance with the written directive and treatment plan prior to the re-initiation of treatment. The AU's presence will maximize quality and safety.

Differences Between the Working Group and Subcommittee's Recommendations About Physical Presence

1. Inclusion of Perfexion™ into the guidance.

   One of the major differences between the WG and subcommittee's recommendation about physical presence is the inclusion of Perfexion™ unit into the guidance. The original subcommittee believed that there were fundamental differences between the Icon™ unit versus the Perfexion™ unit to warrant separate physical presence requirements. These differences include the option to treat with a thermoplastic frameless mask unlike the Perfexion™ unit, CBCT which provides stereotactic reference for patient setup, and HDMM for mask-based treatments. The committee also agrees that many components of the machine are similar, especially the location of the collimator inside the machine, the various positions to turn the beam on and off, and treatment table. Given these engineering similarities, the Perfexion™ unit and Icon™ unit are licensed under 10 CFR 35.1000, unlike the model B and C units which are licensed under 10 CFR 35.600. After discussion about the pros and cons of including both Perfexion™ and Icon™ under similar guidance, the subcommittee supported this recommendation.

2. An AMP and either an AU or a physician, under the supervision of an AU, who has been trained in the operation and emergency response for the unit, will be physically present during continuation of all treatments.

   The subcommittee proposed that physical presence be modified by allowing the AU to be present in the department during treatment, which was defined to be within a 2-minute walk of the console area and immediately available to come to the treatment room after initiation of treatments. The WG and management were not supportive of the 2-minute walk as this was felt to be very ambiguous, which would be difficult to enforce. The WG's proposed physical presence requirement is similar to that of HDR as described in 10 CFR 35.615(f)(2). In addition, the proposed physical presence requirement included both the Perfexion™ and Icon™. Since the guidance proposal includes both Perfexion™ and Icon™, the subcommittee believes similar physical presence requirements to that of HDR is an appropriate alternative to the subcommittee proposal.

3. Our subcommittee also proposed that at the conclusion of treatment, the AU must be present at the Icon™ console to discuss any treatment or patient issues with the patient, AMP and nurse.

   Upon further consideration and deliberation of this recommendation, we conclude that this constitutes a best practice that the NRC should not mandate. In addition, this would be difficult to regulate given the variations in medical practice. The subcommittee does, however, believe that the practice of discussing and reviewing any treatment or patient issue with the patient, physicist, and nurse, does enhance quality, patient experience and outcomes for future patients.

Specific comments

Page 3, section 4.1, 2nd paragraph: Delete "**In accordance with the previously issued licensing guidance for the Perfexion**" and delete "**after July 1, 2009**."

Page 3, section 4.1, 2nd paragraph, last sentence: Replace with "**The written attestation is not required for individuals who hold certification by a recognized specialty board or are already authorized for use of other gamma stereotactic radiosurgery units**."

Page 4, section 4.1, section 3): last sentence, replace with: "**The written attestation is not required for individuals who hold certification by a recognized specialty board or are already authorized for use of other gamma stereotactic radiosurgery units**."

Page 5, 1st paragraph: delete "all other" from 2nd sentence. Should read "**For physicians applying**"

Page 5, 1st paragraph, 3rd sentence- should read: a written attestation **is required** from a preceptor

Page 6, 6, 3rd paragraph, 2nd sentence: delete "**all other**"

Page 17, section 6.4: The grandfathering provision should apply to Icon™ authorized users

Summary:

Although the scope and recommendations from the WG are different than the original subcommittee report on Physical Presence Requirements for the Leksell Gamma Gamma Knife® Icon™, we endorse the Leksell Gamma Gamma Knife® Perfexion™ and Leksell Gamma Gamma Knife® Icon™ licensing Guidance with the caveats noted above. Given the proposed guidance, it is imperative that a culture of safety and quality with checks and balances at every level exists to ensure that the safest and most effective care is delivered to patients while simultaneously protecting the workers and public. Licensees are encouraged to continue to audit and monitor their programs and adopt best practices including a high reliability system approach[4] to mitigate MEs. The subcommittee recommends that the ACMUI and NRC review for any negative trends that may occur as a result of this change in guidance.

Respectfully submitted, August 31, 2018
Subcommittee to review the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance, Advisory Committee on the Medical Uses of Isotopes (ACMUI), Nuclear Regulatory Commission (NRC)

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[4] Reason J. Human error: models and management. BMJ 32:768-770, 2000

Special Presentation

to

Dr. John Suh

NO HANDOUT

Thoughts on Leaving the ACMUI

NO HANDOUT

Special Presentation

to

Dr. Philip Alderson

NO HANDOUT

Thoughts on Leaving the ACMUI

NO HANDOUT

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Yttrium-90 Microsphere Brachytherapy Licensing Guidance

Katie Tapp, Ph.D.
Medical Radiation Safety Team

September 21, 2018

Agenda

- Status of Y-90 Microsphere Licensing Guidance (LG) Revision 10
- Evaluation of Y-90 Microsphere Medical Events
- Comprehensive Training and Experience (T&E) Evaluation

Status of Y-90 Microsphere LG Revision 10

Draft Revision 10

- On November 1, 2017, NRC issued draft Revision 10 of the LG for public comments
- On July 16, 2018, 10 CFR 35 final rule was published
- The NRC/OAS working group is in the process of reviewing the public comments and final rule to make applicable changes to the draft LG

Public Comments

- 133 commenters submitted comments
- 103 commenters used the same template letter
- Majority of commenters provided comments on the manufacturer training pathway ("pathway 2")

Pathway 2 Comments

- Majority of commenters recommended retention of pathway 2
  - Manufacturers have vast experience and can provide consistent training
  - On-sight training of the entire team promotes patient safety
  - Concerns regarding training facilities
  - Majority of commenters recommended retention of pathway 2

Pathway 2 Comments

- 4 commenters recommended removal of pathway 2
  - Consistent with other modalities
  - Ensures trainers would be physicians
  - Too strong of industry push and removal of the pathway would support independent physician practice decision

Additional Public Comments

- Also received comments on:
  - written attestation,
  - new ABR board certification,
  - medical events
  - RSO training,
  - post treatment surveys,
  - possession limits,
  - Other Authorized User (AU) training requirements

Finalization of Revision 10

- NRC/OAS WG will provide the ACMUI the draft LG for comments and recommendations
- NRC/OAS WG will provide the draft licensing guidance to regions and states for their comments
- Congressional Review Act Review

Evaluation of Y-90 Microsphere Medical Events

Medical Event Evaluations

- Presented at the Agency Action Review Meeting to the Commission on June 19, 2018
- Evaluation was completed as NRC staff noted an increase in Y-90 microsphere medical events

Medical Event Evaluation (Cont.)

- Examined 3 specific areas:
  - Regulatory requirements
  - Use of post-treatment images for determining dose delivered
  - Potential licensee performance trends

Medical Event Evaluation Conclusions

- Requiring post-treatment imaging was not recommended
- No negative performance trends or regulatory gaps were identified
- Number of medical events reported have increased over time, but this increase is commensurate with the increase of Y-90 procedures

Comprehensive T&E Evaluation

Reason for Comprehensive T&E Evaluation

- Numerous public commenters stated:
  - Manufacturer representatives provide better training than AUs
  - There is a need for onsite team training
- Recent enforcement actions and inspector insights show possible AU knowledge gaps in written directives, ordering, medical event evaluations, and calibration

Current Training Requirements for Y-90 Authorized Users

- Multiple pathways
  - Nuclear Medicine Physicians,
  - Radiation Oncologist, and
  - Interventional Radiologists (IR)
- Complete manufacturer or AU provided training

Current Training Requirements for Y-90 AUs

- Meet 10 CFR 35.390 or 35.490 requirements, and
- Have training in the operation of the delivery system, safety procedures, and clinical use provided by:
  - an AU, including 3 hands on cases
  - a manufacturer representative, including 3 in-vitro cases and 3 hands on cases

Current Training Requirements for Y-90 IR

- Board Certified or 3 years supervised diagnostic radiology and 1 year supervised interventional radiologist
- 80 hours classroom and laboratory training for byproduct material, including Y-90 microspheres

Current Training Requirements for Y-90 AUs

- Work experience under supervision of an AU or manufacturer representative training
- Training in the operation of the delivery system, safety procedures, and clinical use provided by:
  - an AU, including 3 hands on cases
  - a manufacturer representative, including 3 in-vitro cases and 3 hands on cases

Evaluation Planning

- Evaluation plan is still under development
- NRC/OAS WG have proposed issuing an Inspection Temporary Instruction to collect more information
- Y-90 evaluation is separate from T&E evaluation directed by the Commission

Path Forward

- NRC/OAS working group plans to complete Revision 10 licensing guidance in FY19
  - Draft will be given to ACMUI for review and comments
- On-going effort to complete comprehensive T&E evaluation will continue after Revision 10 is completed.

Acronyms

- ABR – American Board of Radiology
- AU – Authorized User
- IR - Interventional Radiologists
- LG – Licensing Guidance
- OAS – Organization of Agreement States
- RSO – Radiation Safety Officer
- T&E – Training and Experience
- WG – Working Group

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Draft USP <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing and Repackaging

Richard Green, Nuclear Pharmacist

Advisory Committee on the Medical Uses of Isotopes

September 21, 2018

United States Pharmacopeia

- Establishes legally enforceable, national standards
- Private, nonprofit standard-setting body for pharmacy and medicine
- Enforceable when recognized and incorporated into laws and regulations

USP NF

The USP Mission

The USP *"promotes public health and benefits practitioners and patients by disseminating authoritative standards and information developed by its volunteers for medicines, other health care technologies, and related practices used to maintain and improve health and promote optimal health care delivery."*

Informational vs. Enforceable

- Chapters numbered above 1000 are termed General Information chapters
- Chapters numbered below 1000 are Official: enforceable by the FDA

Enforcement of Standards in USP Chapters

- FDA could enforce, but seldom visits pharmacies, hospitals or clinics without cause.
- Boards of Pharmacy are enforcing and some have promulgated regulations in parallel
- CMS & Deemed Accreditation Bodies are inspecting for compliance during accreditation visits
  - American Osteopathic Association / Healthcare Facilities Accreditation Program (HFAP)
  - Center for Improvement in Healthcare Quality (CIHQ)
  - DNV GL - Healthcare (DNV GL)
  - The Joint Commission (TJC)

Radiopharmaceuticals are currently subject to the Standards in USP <797>

- Since 2004

  "The standards in this chapter are intended to apply to all persons who prepare CSPs and all places where CSPs are prepared (e.g., hospitals and other healthcare institutions, patient treatment clinics, pharmacies, physicians' practice facilities, and other locations and facilities in which CSPs are prepared, stored, and transported). Persons who perform sterile compounding include pharmacists, nurses, pharmacy technicians, and physicians."

Radiopharmaceuticals are currently subject to the Standards in USP <797>

"These terms recognize that most sterile compounding is performed by or under the supervision of pharmacists in pharmacies and also that this chapter applies to all healthcare personnel who prepare, store, and transport CSPs. For the purposes of this chapter, CSPs include any of the following:

(1) Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, …"

USP <797> is currently undergoing revision

- Initially, the proposed chapter revision was published for public comment from Sept. 25, 2015 to Jan. 31, 2016.
- During the public comment period, USP received more than 8,000 comments from more than 2,500 stakeholders.
- <797> Pharmaceutical Compounding—Sterile Preparations has described standards for the entire spectrum of CSPs. Standards for radiopharmaceuticals have been addressed at various levels within <797>, but it has been difficult to develop and maintain standards for radiopharmaceuticals in this manner due to the scope of <797> and the unique characteristics of radiopharmaceuticals.

USP Stakeholder Workshop on Radiopharmaceutical Compounding

- Held at USP Headquarters on Feb. 1, 2017
- Invited participants included representatives from:
  - Chemical Medicines Monographs 4 Expert Committee.
  - Compounding Expert Committee
  - Nuclear Pharmacists in hospital, commercial, and academic settings
  - FDA
  - SNMMI Council on Radiopharmaceuticals
  - USP Staff
- Practitioner stakeholders were strongly in favor of developing a separate chapter for radiopharmaceutical compounding

Formation of Expert Panel

- Call for Candidates sent June 2017
- More than **60** applicants for the Expert Panel

Formation of Expert Panel

- **Preferred candidate characteristics**
  - Nuclear pharmacy experience in commercial setting
  - Nuclear pharmacy experience in a hospital setting
  - Experience teaching nuclear pharmacy (academic setting)
  - Experience interacting with State Bards of Pharmacy
  - Hold Board Certification in Nuclear Pharmacy
  - Participant it USP Stakeholders Roundtable meeting
  - Participant at FDA listening sessions
  - Members of CHM4 Expert Committee and Compounding Expert Committee
  - Work for a regulatory agency

Selected <825> Expert Panel

David Barnes Δ	Brenda Jensen *	James Ponto †Δ
Allegra DePietro Δ	Ravi Kashwal #	Sara Rothman #
Wendy Gallbraith Δ	Patricia Kienle *	Vivian Loveless Δ
Fred Gattas Δ	Paul Mahan Δ	Steve Zigler †
Richard Green Δ	Rezaul Mannon	

USP staff:
Domenick Vicchio, Ravi Ravichandran, Gerald Hsu, James Austgen

† member, USP Chemical Medicines Monograph 4 Expert Committee
* member, USP Compounding Expert Committee
\# FDA representative
Δ Board Certified Nuclear Pharmacist (BCNP)

Representation Within <825> Expert Panel

Institutional Nuclear	Commercial Nuclear	Academia	Regulatory	Consultant	Hospital Pharmacy
3 Members	**5 Members**	**1 Member**	**3 Members**	**1 Member**	**1 Member**

Objective of <825>

- To provide clear and effective USP public standards that meet patient and practitioner needs for compounded sterile radiopharmaceuticals today and in the future. The proposed new general chapter will delineate compounding activities for radiopharmaceuticals and provide standards associated with these activities. When complete, General Chapter <825> will contain standards for this class of products.

Draft USP Chapter <825>

- Released for public comment July 27, 2018

"This chapter applies to all practice settings where radiopharmaceuticals are prepared, compounded, dispensed, or repackaged. Practice settings consist of state-licensed nuclear pharmacies, federal nuclear pharmacy facilities, and other healthcare facilities, including, but not limited to: nuclear medicine departments in hospitals and clinics, nuclear cardiology clinics, and other specialty clinics."

Draft USP Chapter <825>

"This chapter applies to all individuals who prepare, compound, dispense, or repackage radiopharmaceuticals. Applicable individuals consist of authorized nuclear pharmacists (ANPs) and authorized user (AU) physicians, as well as individuals working under their supervision. This includes, but is not limited to, student pharmacists, nuclear pharmacy technicians, nuclear medicine technologists and students, and physician residents and trainees."

<825> Contains

- Provides uniform minimum standards for the preparation, compounding, dispensing, and repackaging of sterile and nonsterile radiopharmaceuticals for humans and animals that occur as part of state-licensed activities. Included are the definition, delineation and description of the following:
  - The various activities related to the provision of radiopharmaceuticals, including preparation, preparation with minor deviations, compounding, dispensing, and repackaging.
  - Requirements for the environment appropriate for each of these activities
  - Qualifications for personnel involved in these activities.
  - Practices that are necessary and balanced to ensure personal safety, environmental safety, and patient safety related to radiation risks and radiopharmaceutical quality

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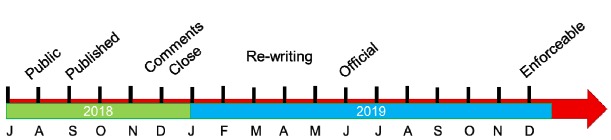
Table of Contents (Cont.)

Timeline for Comments and Becoming Official

- Released for public comment July 27, 2018
- USP will host an open microphone session to discuss <825> on Oct. 10, 2018.
- This proposed new General Chapter will be published in *Pharmacopeial Forum* 44(5) [Sep-Oct 2018] pursuant to section 7.02 of the Rules and Procedures.

Timeline for Comments and Becoming Official

- The comment period for this revision ends on Nov.30, 2018.
- In the absence of any adverse comments the proposed chapter will become official on Dec. 1, 2019.



Heads Up for NRC, Agreement States and ACMUI

- The comment period closes Nov. 30, 2018
- Chapter <825> will become official June 1, 2019
- Chapter <825> will become enforceable Dec. 1, 2019
- RAM licensees will likely be evaluating their practices, infrastructure, equipment, training etc. for compliance with the standards in <825>
- In some cases this may necessitate a RAM license amendment to modify facilities, equipment, practices, etc.

Resources

Link to the USP page to download the proposed chapter <825>, as well as to submit comments:
www.usp.org/chemical-medicines/general-chapter-825

Link to the SNMMI recommendations to the USP <825>:
http://snmmi.files.cms-plus.com/SNMMI-USP-Recommendations-Final_2016.pdf

Acronyms

ACMUI	Advisory Committee on the Medical Uses of Isotopes
ANP	Authorized Nuclear Pharmacist
AU	Authorized User Physician
BCNP	Board Certified Nuclear Pharmacist
BUD	Beyond Use Date
CHM4	Chemical Medicines Monographs 4 Expert Committee
CIHQ	Center for Improvement in Healthcare Quality
CMS	Centers for Medicare & Medicaid Services
CSP	Compounded Sterile Preparation
DNV	GL - Healthcare

Acronyms (Cont.)

FDA	Food and Drug Administration
HFPA	American Osteopathic Association / Healthcare Facilities Accreditation Program
PEC	Primary Engineering Control
SNMMI	Society of Nuclear Medicine and Molecular Imaging
SRPA	Segregated Radiopharmaceutical Processing Area
TJC	The Joint Commission
USP	United States Pharmacopeia
<797>	USP General Chapter, Pharmaceutical Compounding – Sterile Preparations
<825>	Draft USP General Chapter, Radiopharmaceuticals – Preparation, Compounding, Dispensing and Repackaging

Medical Team Updates

Lisa Dimmick
Team Leader Medical Radiation Safety
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State, and Tribal Programs
Office Nuclear Material Safety and Safeguards

Topics

- Commission Papers
- Rulemaking activities
- NRC-Agreement State (AS) Working Groups
- Guidance Documents

Commission Papers

1. SECY-18-0015, "Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release After Radioisotope Therapy," January 2018
2. SECY-18-0037, "Review of the Emerging Medical Technologies Program," March 2018
3. SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817," August 2018

SECY-18-0015

- Provides the Commission with staff's evaluation of the program for regulating patient release after radioisotope therapy.
- Presents the results from dose modeling calculations, reviews of published literature, and extensive stakeholder outreach.
- Staff concluded that the current patient release program is protective of public health and safety, and that rulemaking to change the release criteria regulations is not warranted.

SECY-18-0015

- Staff determined that a comprehensive update to guidance, as well as updates to the equations and methodologies described in the guidance for calculating dose to members of the public from released patients, is warranted.
- Updating the NRC guidance with current scientific knowledge would lead to more accurate estimates of public doses from released patients, resulting in better licensee decisions regarding the timing, circumstances, and risks associated with patient release following byproduct material administration.

SECY-18-0037

- Provide the Commission with the results of the staff's review of the emerging medical technologies program. The paper included list of past, in process, and anticipated staff reviews of emerging medical technologies and resource estimates for the reviews to include guidance development.

Examples of Past Reviews

- **NorthStar Medical Radioisotopes, LLC RadioGenixTM Molybdenum-99/ Technetium-99m Generator System** –February 2018
- **Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator** –July 2017
- **Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes** –October 2016
- **Leksell Gamma Knife® PerfexionTM and Leksell Gamma Knife® IconTM** –May 2016
- **Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres®**(Revision 9) – February 2016

Examples of Past Reviews not 35.1000

- **Lutetium-177 dotatate** – determined to be licensed under 10 CFR 35.300 in June 2018
- **SalutarisMD® Manual Radionuclide Eye Applicator** – determined to be licensed under 10 CFR 35.400 in October 2017
- **Radium-223 Dichloride** – determined to be licensed under 10 CFR 35.300 in January 2013

Examples of In-Process Reviews

- **MASEP Infini ™** cobalt-60 stereotactic radiosurgery for treating brain tumors and lesions
- **GammaPod ™** cobalt-60 stereotactic radiotherapy for treating breast cancer
- **Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres®** – updating existing licensing guidance (Revision 10)
- **Leksell Gamma Knife® Perfexion ™ and Leksell Gamma Knife® Icon™** – updating existing licensing guidance (Revision 1) to address physical presence requirements.

Examples of Anticipated Reviews

- **Phosphorus-32** OncoSil microparticles for advanced pancreatic cancer
- **Thorium-227** antibody therapy for treatment of lymph node, prostate, and breast cancer
- **Radium-224** as Diffusing Alpha-emitters Radiation Therapy (DART) for treatment of solid tumors by alpha particles

SECY-18-0084

- This paper provides the initial results, status, and next steps related to the NRC staff's evaluation of T&E requirements for administering different categories of radiopharmaceuticals for which a written directive is required in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material," Subpart E, "Unsealed Byproduct Material—Written Directive Required."

Rulemaking

1. 10 CFR Part 35 Final Rule, "Medical Use of Byproduct Material – Medical Events Definitions, Training and Experience, and Clarifying Amendments"
2. Naturally-Occurring and Accelerator-Produced Radioactive Materials (PRM-30-66)

Part 35 Timeline – Status & Implementation

July 16, 2018	Final rule and guidance issued and published in the *Federal Register* (83 FR 33046).
October 2018 — March 2019	Training sessions via webinar • NRC staff • NRC licensees • Agreement States (AS) • MML and Permittees (NRC will communicate notice of training)
January 14, 2019	Final rule **effective** for NRC licensees and MML compliance
3 years from effective date of final rule	Final Rule effective for AS and AS licensees compliance

Final Rule – 10 CFR PART 35 Revisions

- Program to determine if a medical event (ME) has occurred
- Separate requirements for identifying and reporting medical events involving permanent implant brachytherapy
- Added molybdenum (Mo) contamination measurement for each elution
- Added reporting requirement for failed technetium (Tc) and rubidium (Rb) generators
- Grandfathered certain board-certified individuals from certain T&E requirements
- Added the Associate Radiation Safety Officers to be named on a medical license
- Added the Ophthalmic Physicist to be named on a license

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Naturally-Occurring and Accelerator-Produced Radioactive Materials (PRM-30-66)

- April 2017 PRM submitted by OAS re: 10 CFR Part 30 Appendix B - used for calculating decommissioning funding requirements
  - Default possession thresholds for unlisted radionuclides are too restrictive
  - In 2005 Congress authorized NRC to regulate discrete sources of NARM; NRC has not updated Appendix B to add NARM radionuclides
  - Regulators either must apply burdensome decommissioning funding obligations or evaluate exemptions – options that hinder introduction of new technologies and adversely affect patient care

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NRC Action on PRM-30-66

- August 2017 – NRC noticed the petition in the *Federal Register* and requested public comment
- 20 comment letters – none opposed the requested rulemaking
- April 2018 – Staff formulated a recommendation and conducted a Petition Review Board (internal)
- Staff is preparing the recommendation and *Federal Register* notice for Commission review and decision

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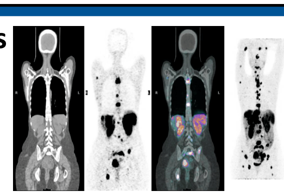
NRC-Agreement State (AS) Working Groups

Current NRC-AS Working Groups

- MASEP Infini™ cobalt-60 stereotactic radiosurgery
- GammaPod™ cobalt-60 stereotactic radiotherapy
- Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres®
- Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™
- Regulatory Guide 8.39, Release of Patients Administered Radioactive Material
- NorthStar Medical Radioisotopes, LLC RadioGenixTM Molybdenum-99/ Technetium-99m Generator System

Guidance Documents

Ge-68/Ga-68 Generators



- The NRC staff foresees the need to provide licensing guidance for other Ge-68/Ga-68 generators
- **The NRC has modified the existing guidance into a non-specific manufacturer licensing guidance.**
- The modifications include minimal word changes to create a "brand neutral" licensing guidance.
- No changes have been implemented in license commitments, breakthrough limits or radiation safety to follow for operation of the Ge-68/Ga-68 generator for generating Ga-68 radiopharmaceuticals.
- RCPD letter soliciting comments to be issued.

NUREG-1556 Series Guidance Documents

- Volume 9— Program-Specific Guidance About Medical Use Licenses
- Volume 13—Program-Specific Guidance About Commercial Radiopharmacy Licenses

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Acronyms

- AS – Agreement State
- CFR – Code of Federal Regulations
- DART – Diffusing Alpha-emitters Radiation Therapy
- FR – Federal Register
- Ga – Gallium
- Ge – Germanium
- MML – Master Materials License
- Mo – Molybdenum
- NARM – Naturally Accelerator Radioactive Materials

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Acronyms

- NRC – U.S. Nuclear Regulatory Commission
- PRM – Petition for Rulemaking
- RCPD – Radiation Control Program Directors
- Rb – Rubidium
- Tc – Technetium
- T&E – Training and Experience

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Open Forum

NO HANDOUT

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ACMUI, Subcommittees, NRC Staff, NRC Management - How the Team Works Under the Federal Advisory Committee Act (FACA)

2018 ACMUI Fall Meeting

September 20-21, 2018

Agenda

- Russell Chazell, Office of the Secretary
  - NRC FACA Committee Management Officer
    - NRC-level FACA overview
- Doug Bollock, Office of Nuclear Material Safety and Safeguards
  - ACMUI Designated Federal Official
    - ACMUI-specific FACA matters

Congressional Mandate for FACA Committees

- Provide advice that is relevant, objective, and open to the public
- Act promptly to complete their work
- Comply with reasonable cost controls and recordkeeping requirements

Role of Federal Advisory Committees

- Committee members provide Federal officials and the Nation with expert information and advice on a broad range of issues affecting Federal policies and programs
- Affords the public an opportunity, as Committee members, to participate actively in the Federal government's decision making process

Complying with FACA

- FACA-chartered Advisory committees must comply with the Federal Advisory Committee Act (Public Law 92-463)
- FACA-chartered Advisory committees must comply with the Government in the Sunshine Act (Public Law 94-409)

Complying with FACA

- FACA-chartered Advisory committees must comply with General Services Administration implementing rules
  (41 CFR Parts 101-6 and 102-3)
- NRC FACA Advisory committees must comply with the NRC implementing rules (10 CFR Part 7)

Complying with FACA

- Each committee must have a Designated Federal Official (DFO) pursuant to 10 CFR 7.11
- The DFO will:
  - Approve meeting agendas
  - Convene meetings
  - Attend meetings
  - Adjourn meetings
  - Chair meetings when directed to do so
  - Ensure compliance with laws and regulations

Advisory Committee on Medical Uses of Isotopes

- Established on July 1, 1958
- Charter renews every two years
  - Current charter expires March 1, 2020
- ACMUI reports to the Division of Materials Safety, Security, State, and Tribal Programs in the Office of Nuclear Material Safety and Safeguards (NMSS/MSST)

Advisory Committee on Medical Uses of Isotopes

- 13 Committee members appointed as Special Government Employees (SGE)
  - Limited to 130 days in any 365 day period
  - Pay capped at daily rate for Level IV of Executive (SES) schedule
- Membership Balance Plan
  - 41 CFR 101-6, Subpart B, Appendix A
    - Includes health care professionals of diverse specialties who represent diagnostic and therapeutic applications of medicine, medical administration, and patient care advocacy

Advisory Committee on Medical Uses of Isotopes

- Terms are set at 4-years with a limit of two terms
- Members are appointed by the Director of NMSS after consultation with the Commission
- Members must comply with
  - Federal Ethics Laws
  - Conflict of Interest Laws

Advisory Committee on Medical Uses of Isotopes

- Subcommittees
  - No standing ACMUI subcommittees
  - Ad hoc subcommittees must report to the full committee, not directly to NMSS/MSST
- Meetings must be open to the public
  - Subject to narrow GISA exceptions
  - Meeting minutes must be kept
- Committee Management Officer:
  - Validates annual report to GSA
  - Ensures Committee compliance with applicable laws and regulations

Questions

Russell Chazell
Office of the Secretary
NRC Committee Management Officer
301-415-7469
Russell.Chazell@nrc.gov

ACMUI Subcommittees, Subcommittee Membership, and the ACMUI Chair

C. J. Palestro, M.D.

Chair ACMUI

ACMUI Subcommittees

- Annual Review of Medical Events
- Training & Experience for All Modalities
- Medical Event Reporting & Impact on Patient Safety Culture
- Medical Event Reporting for All Modalities Except PIB (combined with former Patient Intervention Subcommittee)
- Patient Release SECY Paper Review

ACMUI Subcommittees

- Y-90 microspheres
- Physical Presence Requirements for Leksell Gamma Knife® Icon™
- Ge-68/Ga-68 Licensing Guidance
- Nursing Mother Guidelines

Annual Review of Medical Events

- Members

  Dr. Ennis (Chair), Dr. O'Hara, Dr. Suh, Dr. Metter, Mr. Ouhib, Mr. Sheetz
- Charge

  To periodically review trends in medical events and to formulate recommendations reduce them

Training & Experience for All Modalities

- Members
  Dr. Metter (Chair), Dr. Suh,
  Dr. Alderson, Ms. Weil, Ms. Shober
- Charge
  To periodically review T&E requirements currently in effect for all modalities and make recommendations for changes as needed

ACMUI Subcommittees To Be Ended

- Medical Event Reporting & Impact on Patient Safety Culture
- Medical Event Reporting for All Modalities Except PIB (combined with former Patient Intervention Subcommittee)
- Patient Release SECY Paper Review
- Y-90 microspheres

ACMUI Subcommittees To Be Ended

- Physical Presence Requirements for Leksell Gamma Knife® Icon™
  Dr. Suh (Chair), Dr. Ennis, Ms. Weil,
  Ms. Shober, Mr. Ouhib
- Ge-68/Ga-68 Licensing Guidance
  Ms. Shober (Chair), Mr. Sheetz, Dr. Metter

ACMUI Subcommittees To Be Ended

- Nursing Mother Guidelines
  Dr. Metter (Chair), Dr. Dilsizian,
  Dr. Palestro, *Dr. Zanzonico*

ACMUI Subcommittees To Be Established

- Bylaws (2018)
- Regulatory Guide 8.39: Release of patients administered radioactive materials (2018)
- Y-90 microspheres (late 2019)

U.S.NRC

Acronyms

- Ga-68 – gallium-68
- Ge-68 – germanium-68
- PIB – permanent implant brachytherapy
- SECY – Office of the Secretary
- T&E – training and experience
- Y-90 – yttrium-90

U.S.NRC

March 2019

Monday	Tuesday	Wednesday	Thursday	Friday
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4	5	6	7	8
11	12	13	14	15
18	19	20	21	22
25	26	27	28	29

April 2019

Monday	Tuesday	Wednesday	Thursday	Friday
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8	9	10	11	12
15	16	17 x	18 x	19 x
22 x	23	24	25 x	26 x
29	30			